

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products)
Liability Litigation,) MD 15-02641-PHX-DGC
)
_____))
)
Lisa Hyde and Mark Hyde, a married) Phoenix, Arizona
couple,) September 20, 2018
)
Plaintiffs,)
)
v.) CV 16-00893-PHX-DGC
)
C.R. Bard, Inc., a New Jersey)
corporation, and Bard Peripheral)
Vascular, an Arizona corporation,)
)
Defendants.)
_____)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 3 - A.M. SESSION

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I N D E X

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(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Yesterday we had a discussion at sidebar about Dr. McMeeking's safety-related opinions and it concluded with my asking plaintiffs to identify the portions of the report that show that. My question this morning is whether that's still an issue and, if so, what we need to cover.

MR. O'CONNOR: And I apologize, Your Honor. I know that we talked about safety, but where that limitation is, I don't think I understand it.

Obviously he has testified and has written in his report that there are safety standards in engineering that should be followed.

Obviously he talks about devices that can be unsafe for the user. In terms of safety he was disclosed to talk about that the -- and his report says the SNF, in his opinion, is a safer design because, in his opinion, it does not have the design deficiencies that the filters like the Recovery, G2, G2X, and Eclipse had.

And I believe that was raised with you in prior

08:33:07 1 motions. And I thought you agreed that McMeeking can testify
2 along those lines.

3 In terms of what he would say for a particular
4 patient, he is not going to come in and say that the
08:33:23 5 Simon Nitinol filter was appropriate for Lisa Hyde, and I
6 wouldn't ask him that.

7 He has said in his case-specific report that the Bard
8 G2X filter is improperly and inadequately designed such that
9 it does not prevent tilt, caudal migration, fracture and
08:33:45 10 perforation, as it lacks adequate safeguards against these
11 failure modes to a reasonable degree of scientific and
12 engineering probability and certainty. The failures of
13 Ms. Hyde's filter resulted from poor design, inadequate
14 testing prior to marketing the filter, and implantation of the
08:34:07 15 filter -- and implantation -- prior to implantation of the
16 filter in Mrs. Hyde, and improper internal assessment of the
17 filter via analysis, including finite analysis and other
18 methods of analysis utilized by Bard.

19 So I believe that sums his opinions in this case and
08:34:26 20 where he's going to go.

21 THE COURT: All right. Ms. Helm, do you have a
22 problem with what Mr. O'Connor just read as an opinion to be
23 stated?

24 MS. HELM: Your Honor, those opinions, to use a term
08:34:40 25 I've heard you say before, are all fair game. My objection

08:34:44 1 was not based on those. My objection was based on a question
2 when Dr. McMeeking was asked what his opinions were in the
3 case and he said that he was going to testify that the IVC
4 filter was unsafe. Not that it didn't meet safety standards,
08:35:02 5 not that it was improperly designed, that it was unsafe or not
6 safe. And we did an extensive word search of all of his
7 reports and all of his depositions, and the Booker and Jones
8 testimony, and the opinion the filter is not safe, the filter
9 is unsafe, the filter is not reasonably safe does not appear
08:35:27 10 anywhere in those reports, the deposition testimony, or his
11 prior testimony.

12 So this is a new opinion. It's a step further than
13 what Mr. O'Connor says he's going to offer. If he's staying
14 limited to what Mr. O'Connor says and not going to offer the
08:35:45 15 opinion that came out of his mouth yesterday when I raised the
16 sidebar, we're okay. But if he's going to go a step further
17 and say the filter is unsafe, not reasonably safe, or
18 something along those lines, that is a nondisclosed opinion in
19 the case.

08:36:05 20 THE COURT: Mr. O'Connor?

21 MR. O'CONNOR: Well, Your Honor, like I said at
22 sidebar, I'll try to stay away from that and I'm sure he will.
23 But I just think those types of words are built in the English
24 language, and they're built in engineering. And in
08:36:20 25 engineering, the basic premise of it is to protect the safety

08:36:24 1 of consumers from devices.

2 And so when he says something is safer than
3 something, the corollary to that is the other must be unsafe.

4 And he's going to talk about things that aren't safe,
08:36:36 5 the testing that was done. Obviously his opinion is that that
6 led to failures, which included tilting, fracture, migration,
7 embolization, and pieces going into places in the body like
8 the heart.

9 I'll try to stay away from it, but I don't think
08:36:54 10 that's an unreasonable summary way to say what his opinions
11 are. Or to say that as a reasonable inference from what he
12 has, all the work he has done.

13 THE COURT: Let me -- let me tell you what I
14 understand from my *Daubert* order, which I read earlier this
08:37:13 15 morning.

16 On page 5 of my order I quote from his report where
17 he states that, and this is a block quote page 5 of my order:
18 That the solutions adopted by a manufacturer should conform to
19 safety principles, and then farther down, he says they should
08:37:40 20 eliminate risks as far as reasonably practicable through
21 inherently safe design and manufacture.

22 I declined to exclude that.

23 He also had opined about -- or appeared to opine
24 about filter complication rates. And it said in his
08:38:11 25 deposition that the medical literature tends to confirm that

08:38:14 1 the filters are dangerous.

2 Defendants moved to exclude Dr. McMeeking's opinion
3 about dangerous complication rates, and plaintiff indicated
4 that it would not elicit any such opinions at trial.

08:38:33 5 And quoting from plaintiffs' response to the *Daubert*
6 motion, which is Docket 7806, they said, "He will not testify
7 that the complication rates are dangerous."

8 And I said in my order we're taking him at his word
9 on that.

08:38:49 10 Finally, the defendants moved to exclude any
11 testimony from Dr. McMeeking that the Simon Nitinol is a safer
12 filter than the Recovery, G2, and similar filters, and I quote
13 that language from his report at page 8 of my order, and I
14 concluded that I cannot say that's inadmissible. I denied the
08:39:15 15 motion to exclude that testimony.

16 And I said at the bottom of page 9, "His opinion that
17 the SNF is safer may well be one factor for the jury to
18 consider, along with, obviously, defendants' arguments."

19 The parties agreed, as I noted at the top of page 10,
08:39:38 20 that there will be no opinion about a particular plaintiff.

21 So Dr. McMeeking cannot say a particular filter would have
22 been safer for Mrs. Hyde.

23 So as I go back through that order, he clearly cannot
24 opine that the filters are unsafe on the basis of complication
08:39:55 25 rates or medical literature. He can use the word "safe" or

08:39:59 1 "safety" when he's talking about principles that are applied.
2 He can testify that based on his analysis of the testing and
3 the design of the filters, the SNF is safer than the other G2
4 family of filters. And in those answers he can use the word
08:40:25 5 "safe" and "safety," in my judgment. He can't give a
6 generalized opinion that when you look at the medical
7 literature of failure rates, the Bard filters are unsafe.
8 Because he's not an expert in that area.

9 I think that's the best line we can draw for purposes
08:40:42 10 of what he's going to say today.

11 And if you think, Ms. Helm, he's violating that in
12 some way, you certainly can raise the issue.

13 MS. HELM: May I ask for clarification of one --

14 THE COURT: Yeah.

08:40:52 15 MS. HELM: The plaintiffs have given us a number of
16 exhibits that use the term "the IVC filter unsafe," "the
17 filter was not reasonably safe." Not that it didn't meet
18 safety standards, not that one filter was safer than another.

19 I understand safe to safer and I'm not -- I'm not
08:41:17 20 challenging that. I understand that he can say the SNF is
21 safer than the G2X. But it's the step further that's not
22 disclosed, and that is that the G2X itself is unsafe. That
23 statement. Or not safe. Or not reasonably safe.

24 I'm not challenging the fact that he can say you have
08:41:37 25 to meet safety standards, you have to do all these things.

08:41:41 1 It's the conclusion that it is a not -- it is a not a safe
2 product that has he has never stated and is not included in
3 his reports.

4 THE COURT: Well, what about his assertion as quoted
08:41:52 5 on page 5 of my order that the filter did not conform to
6 safety principles?

7 MS. HELM: I think that's fine. I agree with you.
8 But that's different than saying the filter is unsafe, the
9 filter is not reasonably safe.

08:42:06 10 That's for the jury to decide because he didn't
11 render that opinion. He can say it didn't conform to safety
12 standards. But he can't -- in my opinion, and I respectfully
13 say that he cannot say it was unsafe. Which is what came out
14 of his mouth when I asked to -- for the sidebar.

08:42:25 15 THE COURT: If he were to say, "Based on my
16 evaluation of this as a design engineer and the noncompliance
17 with basic design principles that I think Bard committed, this
18 wasn't a safe design, this was an unsafe filter," what's
19 wrong with that?

08:42:41 20 MS. HELM: That's not disclosed in his report. He
21 never says that. He's never gone that far in his report, his
22 deposition, or his testimony.

23 It's that -- it's taking that next step. He says --
24 he can say --

08:42:56 25 THE COURT: Let me interrupt you for a minute,

08:42:57 1 Ms. Helm. If he says this filter did not conform to safety
2 principles, it violated safety principles, how is that any
3 different from saying it was an unsafe design?

4 MS. HELM: Because, Your Honor, I think that the
08:43:15 5 question of whether it violated safety principles and which
6 ones and all of that is a different conclusion than you can
7 violate a safety principle and not necessarily have an unsafe
8 design. And he hasn't taken it to that step.

9 I think it's allowing him to go a step further than
08:43:36 10 he has gone previously in his report or in his deposition. Or
11 his prior testimony.

12 THE COURT: I think I understand your argument. I
13 don't agree with it. I think he can say based on an
14 engineering evaluation his opinion is this product was not a
08:43:50 15 safe design, it wasn't a safe filter. He can't say it based
16 on complication rates, he can't say it based on medical
17 literature because he's not an expert there.

18 MR. O'CONNOR: And I won't have him say that. And we
19 weren't planning on that.

08:44:07 20 Part of the problem with these disclosures 24 hours
21 sometimes my work product goes and my thought process goes.

22 But I just want to raise one other issue, Your Honor,
23 just so we're all on the same page. He's not going to talk
24 about complication rates from the literature, but one thing
08:44:21 25 you did note that was appropriate for him to do is rely on

08:44:25 1 Dr. Betensky's opinions regarding the Simon Nitinol filter as
2 a safer device, and his opinion was that his own independent
3 engineering assessment of the Simon Nitinol --

4 THE COURT: What are you reading?

08:44:38 5 MR. O'CONNOR: I'm reading from your order, page 10.

6 Right here. It's the paragraph right before your
7 concluding paragraph.

8 THE COURT: Well, what I'm saying in that paragraph,
9 I think, Mr. O'Connor, is that Dr. McMeeking can give an
08:45:15 10 opinion based on his own independent engineering assessment of
11 the SNF and of the G2 and Recovery filters. That's on lines 8
12 and 9. I think he needs to stay within the area of his
13 expertise, which is engineering and design.

14 MR. O'CONNOR: I agree. I just wanted to point that
08:45:35 15 out to you.

16 THE COURT: Okay.

17 MR. O'CONNOR: I mean, it's conceivable he may say
18 things he looked at and reviewed, it was Dr. Betensky's
19 report, and that also showed what his engineering analysis
08:45:47 20 found.

21 THE COURT: But he shouldn't be repeating
22 Dr. Betensky's opinions.

23 MR. O'CONNOR: I won't -- I'll do the best I can on
24 that, and I don't think he will.

08:45:55 25 THE COURT: Okay.

08:45:55 1 MR. O'CONNOR: I certainly can't do it anyway.

2 THE COURT: All right. Do we have other issues that
3 we need to take up this morning?

4 MS. HELM: It's not an issue, Your Honor, but we have
08:46:04 5 the jury instructions that you asked for, and if it's okay,
6 there's a little bit of an explanation, we've caught a typo in
7 the instructions, and we couldn't find one that was on your
8 list. But I brought the books with me, so if you figure out
9 what it is --

08:46:19 10 THE COURT: That would be great. Yeah, we're going
11 to try to use those to craft our jury instructions.

12 Anything from plaintiffs that we need to raise?

13 MR. O'CONNOR: Nothing else.

14 I advised counsel that I think the order's going to
08:46:31 15 be this morning, and like anything in trial could change, but
16 I think we're going to try to finish Dr. McMeeking and then
17 we're going to play Dr. Asch's video testimony. Then I
18 believe Dr. Betensky's coming down, and then Mr. Randall from
19 Bard will be the last witness we intend to call today.

08:46:51 20 THE COURT: Okay. Betensky is the other live expert
21 who will testify?

22 MR. O'CONNOR: Betensky's a live expert. Apparently
23 there's a travel issue with her this morning. And so that's
24 why we're going to -- we need to play videos anyway, so we're
08:47:05 25 going to put the Asch video on, which I thought was 60

08:47:07 1 minutes.

2 Does that sound right?

3 MR. ROGERS: I don't know.

4 THE COURT: Did you say six zero minutes?

08:47:18 5 MR. O'CONNOR: 60. Six zero.

6 THE COURT: A video deposition?

7 MR. O'CONNOR: I'm just the messenger on that one.

8 THE COURT: All right. I may have you both give the

9 jury an official apology for making the jury sit through a

08:47:31 10 60-minute video.

11 MR. O'CONNOR: I share a similar opinion.

12 THE COURT: Okay.

13 All right. I'll come in at 9:00 when the jury's

14 here.

08:47:38 15 MS. HELM: Oh, Your Honor, I --

16 THE COURT: Go ahead.

17 MS. HELM: I just want to raise this. Yesterday
18 during the sidebar, one of the long sidebars, I could hear a
19 lot of it. I actually --

08:47:50 20 MR. ROGERS: At counsel table.

21 MS. HELM: At counsel table. I actually heard you
22 say, "I'm dividing the time in half." So I just wanted to
23 raise the issue. I don't think the jury can hear it, but I --
24 just sitting here I could hear it. So I wanted everybody to
08:48:02 25 be mindful of that.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

08:48:04 1 THE COURT: Okay. All right. Thanks for that.

2 All right. We'll see you in ten minutes.

3 (Recess was taken from 8:48 to 9:00. Proceedings resumed
4 in open court with the jury present.)

09:01:23 5 THE COURT: Thank you. Please be seated.

6 Good morning, ladies and gentlemen.

7 JURORS: Morning.

8 THE COURT: Thank you for being here. We're going to
9 continue where we left off with the testimony of

09:01:32 10 Dr. McMeeking.

11 Mr. O'Connor, you may proceed.

12 MR. O'CONNOR: Thank you, Your Honor.

13 ROBERT McMEEKING,

14 recalled as a witness herein, after having been previously
09:01:36 15 sworn or affirmed, was examined and testified as follows:

16 D I R E C T E X A M I N A T I O N (CONTINUED)

17 BY MR. O'CONNOR:

18 Q Dr. McMeeking, we were going to talk today about the way
19 calculations can help engineers understand stress and strain.

09:02:20 20 Do you recall that?

21 A Yes, sir, I do.

22 Q Before we get there, did you review testing done by Bard?

23 A Yes, I did.

24 Q And did you list the testing in your reports that you
09:02:29 25 determined were inadequate?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:02:31 1 A I did.

2 Q Did you discuss the testing in your reports?

3 A Yes, I did.

4 Q Thank you.

09:02:36 5 All right. So let's talk about how that works, how
6 can calculations by hand or by computer give an engineer, give
7 a medical device company some indication of stress and strain?

8 A Well, as I explained yesterday, stress is something that
9 represents the level of forces that are experienced by devices
09:03:03 10 and structures. And strains, strain characterizes the level
11 of distortion and deformation that such a body will
12 experience. And these -- this information is important to
13 determine whether such a device will fail in some way.

14 And using the principles of physics, it's possible to
09:03:29 15 calculate the level of stresses and strains in an object. And
16 one does that by applying what are called Newton's laws of
17 motion. And specifically balance of forces is what is used in
18 the calculation. And the principles of how material will move
19 around within the structure.

09:03:52 20 The other two pieces of information which are needed
21 is the information about the geometry of the object and the
22 information about the way that the material behaves. And as I
23 pointed out yesterday, some materials behave in a very
24 compliant way and other materials behave in a very stiff
09:04:15 25 manner, such as the steel rod. So that's -- the kind of

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:04:21 1 property of the material that has to go into the calculation.

2 So then one also determines the environment that the
3 device will experience and the forces and displacements which
4 will be imposed on that device. And one also looks at

09:04:42 5 potential problems that the device will have and the failure

6 modes which it is likely to experience. And doing the

7 calculation in the computer or doing the calculation on a

8 piece of paper will bring all that together to generate

9 information specifically about the stresses and strains, and

09:05:01 10 then one can decide from the information about the properties

11 of the materials whether those stresses and strains are too

12 high and whether they will cause the material, for example, to

13 fracture or experience fatigue damage.

14 In addition, one can look at things like stability.

09:05:23 15 For example, if I try and stand the dowel on its end, it will

16 fall down. That's an example of instability. So one can look

17 at the question of whether the device is stable, and although

18 it's not quite the situation that we're talking about, one can

19 also look at whether the device will move in some way as a

09:05:43 20 result of the forces which are being applied to it.

21 And the only difference between doing the calculation

22 on a piece of paper and doing it in the computer is that on

23 the piece of paper one can use calculus and algebra to do the

24 calculations and then finish it off, for example with a

09:06:04 25 calculator. Whereas in the computer, the computer is simply

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:06:07 1 an enormous arithmetic hog and it carries out all the
2 calculations arithmetically that enable it to come up with the
3 solutions to the problem that you've set for it.

4 Q Now, those calculations, does that include what you said
09:06:25 5 was finite element analysis?

6 A Yes. The calculations done in the computer are
7 specifically finite element analysis calculations.

8 Q Did you perform the calculations in this case?

9 A Yes, I did. I calculated finite element analysis
09:06:39 10 calculations.

11 Q Is there a way -- I know you have filters with you. Have
12 you done these type of calculations for the G2 line of
13 filters?

14 A Yes, I have.

09:06:47 15 Q Have you done it for the Recovery?

16 A I've done it for the Recovery. And I have done
17 calculations for the G2, which are valid for the G2X and the
18 Eclipse filters.

19 Q And as you did your calculations, did you have specific
09:07:06 20 failures in mind that you were looking at?

21 A Yes. One of them is whether the filter will experience
22 fatigue damage that will cause it to break. And I can
23 illustrate that with my paper clip.

24 I'm sure you've probably all done this yourself, but
09:07:26 25 if I take this paper clip and I bend it back and forth a

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:07:32 1 little bit, I can do that for a long time. And I can also
2 compute the strains and stresses which the paper clip are
3 experiencing. And I can look at information about the way the
4 material behaves and I can decide whether the strains and
09:07:49 5 stresses which I'm applying are big enough to break the
6 filter -- sorry, to break the paper clip in a modest period of
7 time.

8 Now, in fact, if I apply very small amounts of
9 bending to the paper clip, it is likely to last tens of
09:08:07 10 millions of bendings. So it will last a long time. Now, if
11 I'm more aggressive with it, I can bend it back and forth like
12 that.

13 But let me return to the small amounts of bending
14 because I forgot to mention something, which is that if I do a
09:08:25 15 small amount of bending, the paper clip springs back to its
16 original shape. That is called elastic behavior, when the
17 object returns to the shape it had before the deformation is
18 imposed.

19 In the case of this steel paper clip, when I bend it
09:08:44 20 a lot it stays bent. That's because we've gone into what is
21 called plasticity. But I can also compute the strains and
22 stresses which are generated by the plasticity, and then,
23 although it is a bit harder to do, I can bend the paper clip
24 back and forth, and from the information that I can compute
09:09:05 25 either on a piece of paper or in the computer, I can determine

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:09:10 1 whether these strains are big enough to cause fatigue fracture
2 to the paper clip in a relatively short period of time.

3 And I can look up information about the material and
4 I would -- from that information I would be able to predict on
09:09:31 5 average how long the paper clip will last in terms of the
6 number of bendings back and forth.

7 If I keep doing this long enough, I think you know
8 that the paper clip will break. And that's an example of
9 fatigue fracture.

09:09:44 10 So one of the failures that I was analyzing in the
11 calculations is the question of whether the Recovery, the G2,
12 the G2X, and the Eclipse filter would fail by fatigue fracture
13 within its useful life in a patient.

14 Q All right. And to do those, you were showing us how you
09:10:09 15 were using your hand to bend the paper clip back and forth.

16 Apply that to a filter. What are you looking at in
17 terms of what is going to cause the filter to undergo that
18 type of fatigue?

19 A Well, to --

09:10:22 20 Q You can use a filter to display that.

21 A Yes, but to answer the question, I think it might be
22 useful to show an illustration of the inferior vena cava and
23 what is around the inferior vena cava.

24 MR. O'CONNOR: Well, let's look at Exhibit 4885.

09:10:52 25 And, Your Honor, I'm really just intending to use

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:10:56 1 this for demonstrative purposes. May I display it to the
2 jury?

3 THE COURT: Any objection?

4 MS. HELM: No, Your Honor.

09:11:02 5 THE COURT: Yes, you may.

6 MR. O'CONNOR: Thank you.

7 BY MR. O'CONNOR:

8 Q Does this help you explain?

9 A Yes, it will.

09:11:10 10 So this is a cross-sectional view of the human body,
11 and it's at the level where the filter is implanted typically.
12 So if you look in the middle slightly above -- slightly more
13 than halfway up, you'll see there's a blue oval-shaped item.

14 Q I think you can draw marks on your screen, but I don't
09:11:35 15 know if --

16 A I can do that, can I?

17 THE COURT: Just with your finger.

18 THE WITNESS: This right here is the inferior vena
19 cava.

09:11:43 20 Can it be erased as well so that it's easier to see
21 if it's gone?

22 THE COURTROOM DEPUTY: Yep.

23 THE COURT: It's gone.

24 THE WITNESS: It's gone.

09:11:51 25 That's the inferior vena cava. That is where the

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:11:53 1 filter is implanted.

2 This is a view of a person looking towards the head,
3 and the top of the filter is typically at the location where
4 this cut has been made in this person's body. And so most --
09:12:12 5 and so the filter is mostly on this side of the picture.

6 Okay?

7 But the filter is attached to the walls of the vena
8 cava by its -- its struts. And I'll let you see a filter in
9 just a second so you can understand that situation.

09:12:35 10 And what's important to realize is that when you
11 breathe, your diaphragm goes down. When you breathe in your
12 diaphragm goes down, and that compresses all of the organs and
13 items which are in your abdomen, and that process squeezes the
14 inferior vena cava. And so the inferior vena cava gets
09:13:00 15 narrower. And then when you breathe out, you're diaphragm
16 goes back up and that allows all of the organs in your abdomen
17 to move again and the inferior vena cava gets wider once more.

18 BY MR. O'CONNOR:

19 Q Is there an engineering term that you call that when there
09:13:21 20 is a motion, a squeezing, that's repetitive in the human
21 anatomy?

22 A Yes. We would describe that as expansion and contraction
23 of the vena cava. Compression and expansion of the vena cava,
24 change of its diameter, change of its width. So there's
09:13:40 25 various ways that we can describe it.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:13:43 1 Q What is cyclic strain?

2 A Cyclic strain is what is caused by those motions when
3 they're imposed on a device such as the filter, and the cyclic
4 designation just means it's repeated over and over and over
09:13:56 5 again.

6 As you know, you breathe many times a minute, and
7 therefore you are cycling your inferior vena cava from a
8 narrow width to a wide width and back again. And that's the
9 reason why it's called cyclic deformation.

09:14:19 10 Q So, Dr. McMeeking, are you telling us that you can take
11 calculations and measure those repetitive forces caused by the
12 expansion and contraction of the vena cava and how the filter
13 will respond to that?

14 A Yes. What one can do is simulate that expansion and
09:14:38 15 contraction in the calculation that you do and put that
16 expansion and contraction on the elements of the filter and
17 then calculate the consequences in terms of strain.

18 Q All right. Are we finished with this demonstrative?

19 A Not quite. I want to make one more comment, which is
09:14:55 20 the --

21 MS. HELM: Excuse me, Your Honor. I don't think
22 there's a question pending.

23 THE COURT: I think we need to proceed by question
24 and answer.

25

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:15:05 1 BY MR. O'CONNOR:

2 Q Well, Dr. McMeeking, when you talk about the anatomy and
3 you talk about the vena cava and you talk about the motions
4 that it imposes on the vena cava filter, is there anything
09:15:11 5 else that's important in your analysis from the perspective as
6 an engineer that you can illustrate with the demonstrative
7 exhibit we're looking at?

8 A Yes. Which is that there are some maneuvers that you
9 undertake in which you squeeze your vena cava by a large
09:15:30 10 amount. For example when you cough, you tend to squeeze your
11 vena cava very severely. If you hold your nose and try to
12 expel air through your ears, for example after you've been on
13 a plane, that's call a Valsalva maneuver, and it can squeeze
14 the vena cava by very large amounts.

09:15:49 15 And another aspect of what is relevant here is that
16 you can see that everything around the vena cava is tightly
17 packed. There's lots of organs and muscles and there's some
18 backbone adjacent to it. And that all adds up to the
19 environment within which the vena cava functions and the
09:16:14 20 filter within it will be experiencing.

21 Q So are you saying that when you are doing engineering
22 calculations and you're looking at stresses and strains that
23 will be imposed on an IVC filter, that you just can't look at
24 a model of the vena cava itself, you have to take into account
09:16:34 25 the tissue and anatomy that is next to the vena cava?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:16:39 1 A That's correct.

2 MS. HELM: Objection, Your Honor. Leading.

3 THE COURT: I think that's a summary question.

4 Overruled.

09:16:45 5 MR. O'CONNOR: I'm sorry --

6 THE WITNESS: Yes, that's correct. Yes, you have to
7 take all that into account.

8 BY MR. O'CONNOR:

9 Q Is that the point you were trying to make?

09:16:52 10 A Yes, that was the point.

11 Q All right. Thank you.

12 Can we talk about the filter now?

13 A Yes.

14 Q Thank you.

09:16:57 15 Can we take this down?

16 A Yes.

17 Q Thank you.

18 So what -- can you show us the IVC filter -- and I
19 think there's an Elmo there that would enlarge it, and just
09:17:13 20 show us or simulate to us how and what features of the IVC
21 filter will be affected by what you just told us about.

22 A Yes --

23 Q Breathing, squeezing, expansion and contraction of the
24 vena cava. Is that what you're saying?

09:17:29 25 A Yes, that's correct. Yes, I can.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:17:31 1 Q Thank you.

2 MR. O'CONNOR: Be careful. There. Thank you.

3 THE WITNESS: So this is an Eclipse filter. It is

4 identical in shape to a G2X. So you can think of this as

09:17:52 5 either a G2X or an Eclipse filter. This one appears blue, if
6 you can see that on the screen.

7 The G2X is a silvery color. So that's the only
8 difference in appearance between the two filters.

9 And if I hold it by one of its arms, you can see that
09:18:15 10 there's a feature on the left which has a hook on it. And
11 that is the cap or sheath or retrieval hook that is at the top
12 of the filter.

13 BY MR. O'CONNOR:

14 Q We're going to talk about the cap later on today.

09:18:35 15 So at this point while you have this up, can you show
16 us that again what you mean when you talk about the cap of the
17 filter?

18 A Yeah. So the cap of the filter is the thicker item at the
19 left end of the filter the way that I'm showing it on the
09:18:54 20 Elmo.

21 Q Is it the -- why don't you just point with your finger to
22 it so we know.

23 A That's the cap.

24 Q And that's the location where the arms and legs of the
09:19:11 25 filter emanate from?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:19:13 1 A That's right.

2 So there are six arms, which are the limbs that have
3 the bend in them just over a third of the way along them. And
4 then there are six legs which are the -- sorry -- which are
09:19:31 5 the longer limbs which have -- you can see curved ends that
6 look like smaller hooks.

7 Q All right.

8 A And these 12 limbs are all gathered together inside the
9 cap, which holds them together and in place.

09:19:50 10 Q Let me just stop you at one point, and this may be
11 appropriate to talk about.

12 This material, I think you mentioned it before, we've
13 heard about it, what is this filter made out of?

14 A This filter is made of a metal alloy called Nitinol, which
09:20:03 15 is almost 50 percent/50 percent mixture of nickel and
16 titanium.

17 Q And knowing the material is that involved, is that
18 information necessary for your calculations?

19 A Yes. It's necessary and important to have that
09:20:21 20 information for the calculations.

21 Q Why?

22 A Because the -- as I mentioned earlier, different materials
23 have different properties, and specifically Nitinol is a
24 material that is known to fail by fatigue fracture. And
09:20:42 25 having the knowledge that the material is Nitinol enables you

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:20:45 1 to consider data on how Nitinol fails by fatigue fracture and
2 therefore take that into account with the results of the
3 calculations that you carry out.

4 Q And when you say data, is there someplace that engineers
09:21:00 5 or medical device companies can go to look at how different
6 materials fail?

7 A Well, there's scientific and engineering literature on the
8 subject. There are papers that are published that summarize
9 the fatigue data for materials such as Nitinol, and there are
09:21:21 10 also handbooks and design books that give that information as
11 well. So this kind of information is summarized in various
12 places.

13 Q Are you able to show us, Dr. McMeeking, and demonstrate
14 with that filter what happens to it while it's in the vena
09:21:41 15 cava that creates the concern about fatigue, stress, and
16 strain?

17 A Yes. So I'm -- I mentioned that the vena cava contracts
18 and expands. And what that means is that -- it's not easy to
19 demonstrate this with this small filter, but what that means
09:22:05 20 is that the arms, for example, are squeezed together and then
21 allowed to expand apart again. They're squeezed together,
22 they're allowed to expand apart again. And that process
23 happens over and over again as you breathe. The same thing
24 happens to the legs. They're squeezed together and then
09:22:29 25 they're allowed to expand. And that process can generate

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:22:35 1 fatigue damage.

2 Q And -- and is there some type of limit of fatigue that you
3 can find a material can withstand and not withstand?

4 A That's correct.

09:22:47 5 Q How do you do that?

6 A If you -- I'm going to use a bigger demonstrative, which
7 is a big spring, to make some of this information clearer.

8 So imagine that my two fingers are the vena cava
9 wall. The vena cava is narrower than the filter. So the
09:23:09 10 first thing I have to do is squeeze the filter to get it
11 between my fingers. It's not easy to demonstrate that under
12 the Elmo, but here's the width of the vena cava between my
13 fingers. There's the width of the filter, which is the length
14 of the spring. I have to squeeze the spring to get it into
09:23:31 15 the vena cava. Now when you breathe the vena cava contracts,
16 when you breathe out it expands. And I can compute how much
17 strain this spring is experiencing as the vena cava expands
18 and contracts.

19 Q If -- go ahead.

09:23:52 20 A If the strain is high, just like the paper clip, the
21 filter will fail by fatigue after a relatively small number of
22 cycles. If the strain, in other words the expansion and
23 contraction, is not so big, then the filter can last many,
24 many cycles of expansion and contraction associated with
09:24:16 25 breathing.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:24:18 1 Q So how do you apply all of that to your calculations?

2 A So you calculate the strains which the filter experiences
3 from the calculations that you do, and then you go to the data
4 for the material and you compare the strain magnitudes and the
09:24:36 5 strain differences that occur with the data in the materials
6 information, and you look at it to decide whether the strain
7 is too big and the device will fail relatively quickly or
8 whether the strain is very low, and if it's very low then the
9 device may be able to last or should be able to last tens of
09:25:01 10 millions of breathing cycles.

11 Q And that's something that you can find and learn and
12 predict through your calculations?

13 A Yes, that's correct.

14 Q All right. So you did the calculations, including finite
09:25:14 15 element calculations and hand engineering calculations; is
16 that right?

17 A That's correct.

18 Q And you were finding what, that the critical point, the
19 critical strain that would result in the fracture of this
09:25:26 20 filter?

21 A Yes. In some of the conditions that I identified as
22 foreseeable conditions that the filter would experience, the
23 strains were quite high. They were very high. And the
24 comparison with materials data indicated that the filter would
09:25:48 25 fail before ten years had passed of breathing within the human

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:25:56 1 body.

2 Q And what did you find?

3 A I found that the results were predicting that the filter
4 would break by fatigue in less than ten years of breathing.

09:26:09 5 Q And were your findings consistent with what you actually
6 saw in this case of Mrs. Hyde's?

7 A Yes.

8 Q And did you look at Bard's testing for fatigue?

9 A I did.

09:26:22 10 Q And what did you look at?

11 A I looked at the tests they carried out for the Recovery
12 filter. I looked at the tests they carried out for the G2. I
13 looked at the tests that they carried out for the G2X. And I
14 looked at the tests they carried out for the Eclipse.

09:26:43 15 Q And what did you find from their tests?

16 A I found that all of those tests were inadequate and were
17 not properly designed to ensure that the information needed
18 would be gathered from those tests.

19 Q How so? Can you tell us in basic terms?

09:27:02 20 A So in the case of Recovery filter, they took the Recovery
21 filter, which is very similar in shape and size to this one.
22 There are detail differences in the shape and size. And they
23 put the filter in a tube. So the tube was simulating the vena
24 cava. They then took the tube and they squeezed the tube by
09:27:30 25 one millimeter to represent the compression on the filter

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:27:36 1 associated with breathing. And then they allowed the filter
2 to expand again by one millimeter. And they did that over and
3 over again. And they -- the filter was in an 18.9-millimeter
4 diameter tube. So it was squeezed to get into that tube, and
09:27:59 5 then further squeezed by one millimeter to represent breathing
6 and then allowed to expand.

7 And the engineers who carried out that test conducted
8 a test in which they imposed 36 million cycles of breathing
9 loading on the filter.

09:28:19 10 Q And was that inadequate?

11 A Well, there's various aspects of the test that were
12 inadequate.

13 One very important aspect of it was that it did not
14 represent worst-case conditions.

09:28:33 15 Q How so?

16 A The filter was placed in the tube so that it was perfectly
17 aligned with the tube. However, filters can tilt. I moved it
18 in the wrong direction. Filters can tilt in the vena cava and
19 that worsens the conditions of the strain levels which the
09:28:59 20 filter will experience, and therefore it represents a worse
21 condition than when the filter is perfectly aligned with the
22 tube.

23 Q And can tilting to even the slightest degree affect that?

24 A Well, tilting, it's a progressive matter. The more the
09:29:17 25 tilting, the bigger the effect. And tilting of a significant

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:29:21 1 amount of such as 15 or 20 degrees would have a notable effect
2 on raising the strains.

3 Another feature that was absent from the test is that
4 the limbs were entirely inside the tube. Now, we know from
09:29:39 5 experience with these filters that the limbs cut through the
6 wall of the vena cava and they protrude outside of the wall of
7 the vena cava. This happens progressively and it happens over
8 time. But you end up with a filter which has the ends of its
9 arms and legs sticking outside, or some of them, sticking
09:30:03 10 outside of the vena cava.

11 That has the effect of imposing larger strains on the
12 filter when you breathe and cause your vena cava to expand and
13 contract.

14 Another feature that was missing from the test is the
09:30:23 15 process called endothelialization occurs with any foreign
16 object which is in the human body, and that's the process in
17 which the body tries to grow tissue over the foreign object
18 and encapsulate it. And that has the effect of glueing the
19 object to the tissue, and the glueing process or the fact that
09:30:54 20 the filter is glued to the vena cava will increase the strains
21 as well.

22 So three features that were missing that lacked the
23 aspect of worst-case conditions were lack of tilt, lack of
24 perforation, and lack of endothelialization.

09:31:10 25 Q All right. So is this a good time to talk about those and

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:31:13 1 show the jury from illustrations how that affects the filter?

2 A No, because there's another aspect of the test which
3 should be mentioned.

4 Q What other aspect is necessary to understand your
09:31:25 5 opinions?

6 A Which is that the test was carried out for only 36 million
7 cycles.

8 Now, if you -- when you breathe, the typical
9 breathing rate ranges from about six breaths per minute to 15
09:31:42 10 breaths per minute. And as you know, after running it can be
11 even higher. But 15 breaths per minute is a reasonable upper
12 end of the spectrum of rates. And six breaths per minute is
13 at the low end. And it's typical when you sleep, for example.

14 But when you're up and about during the day, you're
09:32:03 15 breathing more like 15 breaths per minute. That's one every
16 four seconds.

17 And if you breathe for ten years at 15 breaths per
18 minute, you perform 80 million breaths in that period. And
19 therefore a test to simulate ten years of breathing, which was
09:32:26 20 the objective of the test, should be undertaken to 80 million
21 cycles of expansion and contraction.

22 As I mentioned earlier, the test was stopped at
23 36 million cycles, which actually represents breathing at six
24 breaths per minute, and therefore the test did not properly
09:32:49 25 simulate ten years of breathing in worst-case conditions,

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:32:53 1 which should be at the upper end of the rate at which you
2 breathe.

3 Q So, Dr. McMeeking, is it necessary for a medical device
4 company to anticipate the failure modes in the design process
09:33:07 5 of a filter?

6 A Yes. And in any device, but including medical implants
7 and medical devices, it's important to anticipate and identify
8 what problems might arise and to determine what failure modes
9 are likely to be a problem with the device.

09:33:29 10 Q All right. Now, in terms of tilting, is this the point we
11 should discuss that and illustrate to the jury so you can show
12 how that will affect the other failure modes?

13 A Yes, this would be a good time to do that.

14 Q One other point. Migration. Can you just discuss that
09:33:48 15 with us real quick?

16 A So migration is the process by which the filter can move
17 in the vena cava. And if it moves in a gross way, the whole
18 thing can move, and so I'm flapping it around a bit fast. It
19 might go towards the head, which is going that way, or it
09:34:10 20 might go towards the foot, which is going that way.

21 Now, in addition, the process of tilting will induce
22 the motion of the -- of the filter. If I can do this
23 carefully, if I tilt such that one of the feet doesn't move,
24 you can see that some of the other feet move towards the --
09:34:39 25 they move to the left on the screen. I know I'm not

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:34:42 1 illustrating this very clearly, but I have some drawings later
2 on I can show you that make this a bit clearer.

3 Q Should we get to those drawings?

4 A Let me say one more thing, which is --

09:34:54 5 MS. HELM: Again, Your Honor, in there's no question
6 pending.

7 THE COURT: Sustained.

8 BY MR. O'CONNOR:

9 Q Okay. Well, let me just ask you this. We were talking
09:35:00 10 about migration. And is there another part of what you're
11 demonstrating that is important to understand your opinions?

12 A Yes, there is.

13 Q What is that?

14 A It's just the process of tilting can lead to migration of
09:35:12 15 the filter towards your feet because it can tilt once and move
16 towards -- move some of itself towards the foot, then it can
17 tilt in the opposite direction and move again towards the
18 foot, and so it can steadily walk down the vena cava towards
19 your feet by that process of tilting multiple times.

09:35:44 20 Q Is stability an important feature in the design of an IVC
21 filter?

22 A Yes.

23 Q What does stability mean?

24 A Well, stability, it covers both migration and tilt and
09:36:01 25 to -- also to perforation, for that matter, because all of

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:36:06 1 those features undermine the ability of the filter to stay in
2 place and perhaps perform its job. So that the tilting
3 process is an instability of the filter. As I pointed out
4 earlier, instability is things like my wooden dowel falling
09:36:29 5 over. If I take the steel rod, I can probably -- I'm not sure
6 if I can do that. If I take the spring, I can stand it up
7 stably.

8 Oh, no, I can't.

9 There. It's standing stably. But if I perturb it a
09:36:50 10 little bit, it will fall over. So that -- that aspect of the
11 behavior is what we call instability and so that we're looking
12 at the lack of stability of the device.

13 And perforation is an instability of the filter as
14 well because it -- the filter wants to expand to its natural
09:37:17 15 shape and it can do that by cutting through the wall of the
16 vena cava.

17 Q All right.

18 Can you talk to the jury about these failure modes by
19 showing them on diagrams?

09:37:36 20 A Yes, I can.

21 Q For illustration purposes.

22 May we see 4342, please.

23 I would like to display this to the jury for
24 demonstrative purposes.

09:37:53 25 MS. HELM: No objection, Your Honor.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:37:54 1 THE COURT: You may.

2 BY MR. O'CONNOR:

3 Q All right, Dr. McMeeking, this is a diagram that will help
4 you explain your opinions about how the Bard filter was
09:38:07 5 defective in terms of the failure modes that you discussed;
6 right?

7 A That's correct.

8 Q And what this illustrates is your opinion on tilting and
9 the relationship of the various failure modes. True?

09:38:20 10 A That's correct.

11 Q So would you explain to us what we're looking at.

12 A So what we're looking at on the left marked A is a G2
13 filter. So it's not the G2X or the Eclipse, but it's the G2.
14 And it is sitting aligned with the vena cava. So you can see
09:38:41 15 that it's straight up and down and it's in a nice place.

16 The illustration B is a tilted filter. So it's gone
17 off axis and is at an angle to the axis of the vena cava.

18 The filter wants to do this because it can spread its
19 arms out by that process and it can expand just the way a
09:39:11 20 spring wants to expand when you squeeze it. If I take this
21 spring and squeeze it, it pushes back on you and that's
22 telling you that it wants to expand again.

23 And if I actually squeeze it hard enough and I wiggle
24 my fingers a little bit, it will jump out of there. And
09:39:35 25 that's the instability associated with that situation.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:39:39 1 And the spring -- sorry. The filter, the filter is
2 simply a spring. If I push on the arms, there's a very small
3 force that resists my pushing on the arms, but it's pushing
4 back on my fingers telling me that the arms want to expand
09:40:00 5 again, just the way that the spring wanted to expand against
6 the compression of my fingers.

7 And so the process of tilting is an expansion process
8 that allows the filter to relax into a preferred shape and
9 generates the instability of tilting that we are describing.

09:40:23 10 Q And so here we're looking at a filter that is slightly
11 tilted. And can you explain to us how that can relate to
12 something like perforation.

13 A Well, if the filter tilts, and it might tilt by a very
14 small amount, the way that the arms are sticking against the
09:40:47 15 wall of the vena cava, that can change. And the way that it
16 can change is because the arms themselves are like needles.
17 They're very narrow. They have a somewhat sharp point. And
18 if the filter tilts, it can be up against the vena cava wall
19 in such a way that the end of the tip of the arm is pushing
09:41:13 20 like a needle against the tissue. And so that can drive the
21 arm through the wall of the vena cava leading to perforation.
22 So tilt can lead to perforation.

23 Q Dr. McMeeking, I apologize, I interrupted you. But just
24 for benefit of all of us here today, when you talk about --
09:41:31 25 and you alluded to this before, but when we talk about the G2,

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:41:36 1 the G2X, and the Eclipse, are these all the same in terms of
2 design?

3 A The G2, the G2X, and the Eclipse are identical in regard
4 to the kind of things that we're talking about. Because the
09:41:52 5 only difference among them is that the G2, which you see on
6 the screen, does not have the retrieval hook. The G2X does
7 have the retrieval hook. And the Eclipse has a different
8 surface finish. But none of those will be -- will have any
9 effects on the instabilities such as tilting, perforation,
09:42:17 10 and -- and what else? Tilt, perforation, and caudal
11 migration. They would not have any influence over those
12 phenomena.

13 Q All right. And is it fair to say that tilt, even a small
14 degree, can start the process of things like perforation?

09:42:40 15 A Yes, that's correct.

16 Q And is that consistent with the work and analyses you've
17 done in this case?

18 A Yes, that's correct.

19 Q All right. And we're going to talk more about Mrs. Hyde's
09:42:50 20 filter, but can you tell the jury, her filter, be it a G2X or
21 there's a suggestion it may have been an Eclipse, how her
22 filter failed?

23 A Well, her filter failed by perforation. It failed by
24 fatigue fracture. A piece of it broke off, an arm broke off,
09:43:09 25 and it broke off near the cap at the top. And that piece

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:43:14 1 migrated to her heart. The filter also experienced, we know
2 it experienced a small amount of tilt and a small amount of
3 caudal migration from the imaging which is available.

4 Q Do you have an opinion whether -- and those are stability
09:43:31 5 issues?

6 A Yes.

7 Q Do you have an opinion whether those filters -- the G2,
8 G2X, and the Eclipse -- were defective in design that resulted
9 in those failure modes?

09:43:42 10 A Yes. It's my opinion that the defects in the design of
11 the G2, G2X, and the Eclipse led to those failures, the
12 failures of tilt, the failures of caudal migration, the
13 failures of perforation, which is a very serious one, and the
14 failure of the filter by fatigue fracture.

09:44:10 15 Q Now, in terms of tilt, is there a way that engineers and
16 medical device companies can determine whether a device will
17 be prone or susceptible to tilt?

18 A Yes, there is.

19 Q How?

09:44:20 20 A Well, there's two ways. One can do calculations to
21 investigate on a theoretical basis, on a calculation basis,
22 the stability or potential instability of the filter.

23 But one can also carry out what are called bench
24 tests to investigate the instability as well.

09:44:40 25 Q And what did you do in your case to analyze them?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:44:45 1 A I did calculations.

2 Q Okay. Did you do bench testing?

3 A I did not do bench testing.

4 Q Why not?

09:44:51 5 A I don't do bench tests. I don't have a laboratory, I
6 don't undertake experiments. I do calculations.

7 Q Was it necessary for you to arrive at your opinions to do
8 bench testing?

9 A No.

09:45:03 10 Q Why?

11 A Because, first of all, the calculations themselves
12 indicated the problem. They indicated that there is a problem
13 and that it's a potential -- it's a failure mode of the
14 filter. But in addition, there are reports in the scientific
09:45:15 15 and medical literature that confirm that filters that have
16 been implanted in patients, that significant fractions of them
17 are observed to tilt. And in addition, there have been many
18 examples of patients in litigation who have experience tilted
19 filters.

09:45:39 20 MS. HELM: Excuse me, Your Honor.

21 THE COURT: Hold on just a second.

22 MS. HELM: May we approach?

23 THE COURT: Yes.

24 If you want to stand up, ladies and gentlemen, feel
09:45:44 25 free.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:45:44 1 (Bench conference as follows:)

2 MS. HELM: We have a stipulation there be no
3 discussion of other lawsuits, and he just plowed right through
4 it. Great big hole. I'd ask for an instruction to the jury
09:46:04 5 that that last sentence be struck and that they be instructed
6 not to consider his testimony on that.

7 MR. O'CONNOR: I agree. I didn't know he was going
8 to go there. I was just asking him how you test for this.

9 THE COURT: All right. How do you propose we phrase
09:46:19 10 the instruction?

11 MS. HELM: I think you instruct them that his last
12 sentence -- you're striking it, they're not to consider it. I
13 don't --

14 THE COURT: They need to know what I'm telling them
09:46:32 15 not to consider. Want me to mention litigation?

16 MR. ROGERS: I was about to say I don't -- don't give
17 an instruction.

18 MS. HELM: I'm being overruled over here.

19 THE COURT: I mean, I don't think I can be specific
09:46:44 20 without mentioning litigation again. The question is do you
21 want me to reinforce that?

22 MS. HELM: What if we go back and you ask me to state
23 my objection on the record and I move to strike his last
24 statement and you grant my objection?

09:46:55 25 THE COURT: They still don't know what's being

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09:46:56 1 stricken because there were two or three ideas in his last
2 statement.

3 MS. HELM: Well --

4 THE COURT: Are you objecting to his saying the
09:47:04 5 scientific and medical literature?

6 MS. HELM: No.

7 THE COURT: That was part and parcel of that
8 statement.

9 MS. HELM: Then he took his truck and blew right
09:47:13 10 through it.

11 THE COURT: I agree.

12 So the question is -- everybody is agreeing that that
13 was error. Do you want me instruct them to disregard the
14 reference to litigation? Which I can do.

09:47:23 15 MR. O'CONNOR: Here's what I will do. When I go back
16 I will say, Dr. McMeeking, I want you to talk specifically
17 about testing that you did and how it relates to this case,
18 and I don't want you to -- and just Bard testing and analysis.
19 And I'll just remind him of that.

09:47:41 20 MS. HELM: Okay. I would -- I mean, I think if I
21 state my objection and move to strike the entire answer and
22 you grant that, you can ask him to rephrase it and you limit
23 it to his testing analysis and literature.

24 MR. O'CONNOR: Well, Bard testing analysis.

09:47:58 25 MS. HELM: Yes, and his review of the literature.

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09:48:00 1 I don't know.

2 MR. ROGERS: He may just blurt it out again if
3 there's no direct comment to him.

4 MR. O'CONNOR: Let me --

09:48:10 5 THE COURT: I could say there was a reference in the
6 last answer to other cases, the jury should disregard that; in
7 this case that's not relevant evidence. And go on. But it's
8 up to you whether you want me to --

9 MS. HELM: It's your call.

09:48:24 10 MR. ROGERS: Just move on.

11 THE COURT: Okay.

12 MR. O'CONNOR: What I will do is I will advise him
13 just to stay with the Bard testing and the Bard analysis and
14 just talk about that. I think that should be sufficient to
09:48:37 15 clue him in and get him back on track.

16 THE COURT: Okay. Let's do that. Thanks.

17 (Bench conference concludes.)

18 THE COURT: Thanks, ladies and gentlemen.

19 BY MR. O'CONNOR:

09:49:01 20 Q Dr. McMeeking, I'm going to ask you questions specific
21 about Bard's analysis and Bard's testing and how it applied in
22 your work. And you talked -- and that's where I think I would
23 like to stay for the next series of questions. Okay?

24 A Okay.

09:49:20 25 Q And you talked about tilting and testing that was done by

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09:49:25 1 yourself; is that correct?

2 A That's correct. I did calc- -- testing by calculation.

3 Q And did Bard do any type of testing?

4 A They did no testing of whether the filter would tilt.

09:49:37 5 Q And do you have an opinion whether that was appropriate?

6 A That was a deficiency in the testing program. They should
7 have investigated the stability of the filter. They could
8 readily have investigated it by doing calculations, and they
9 could readily have developed a bench test that would

09:49:59 10 investigate whether the filter would remain straight or would
11 tilt when put in a simulated vena cava and then pushed to see
12 whether it would tilt.

13 Q All right. Now, can we leave this illustration and go to
14 perforation?

09:50:19 15 A Yes.

16 MR. O'CONNOR: Can we put up slide 4349, please.

17 BY MR. O'CONNOR:

18 Q And, Doctor --

19 MR. O'CONNOR: May I use this as a demonstrative to
09:50:36 20 display to the jury for this?

21 THE COURT: Any objection?

22 MS. HELM: Not as a demonstrative, Your Honor.

23 THE COURT: All right. You may use it.

24 BY MR. O'CONNOR:

09:50:45 25 Q Now, Dr. McMeeking, this is a demonstrative that

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09:50:48 1 illustrates perforation; correct?

2 A That's correct.

3 Q But I think you told us that the filter in Lisa Hyde
4 fractured at the arm.

09:50:56 5 A That's correct.

6 Q And this is actually showing legs perforating; is that
7 correct?

8 A This is showing legs perforating, but the arms perforated
9 as well.

09:51:05 10 Q And tell us about what you did to assess Bard filters and
11 the defective design in terms of perforation.

12 A So this is the result of a finite element calculation, and
13 it's one that I carried out. And what I did was that I --
14 I -- in the computer, I implanted a filter, this is a G2, but
09:51:33 15 there's no difference in terms of the process associated with
16 the G2X and the Eclipse. They would have -- they would behave
17 in the same way. So this calculation represents the G2X and
18 the Eclipse just as well as it represents the G2.

19 But what I did was I took the computer and defined
09:51:53 20 the shape of the filter, I defined the size of the vena cava,
21 and I defined the material properties of the -- of the
22 Nitinol, and I used what are called its superelastic
23 properties in this calculation.

24 Q Let me ask you, that calculation, is that standard
09:52:13 25 methodology for engineers --

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09:52:15 1 A Yes.

2 Q -- who would look at issues of a medical device such as a
3 filter and its propensity to tilt and perforate?

4 A Yes. Yes.

09:52:23 5 So what I did was I put the filter in the vena cava,
6 and first it was straight up and down, just as the previous
7 illustration showed on the left.

8 And then what I did was I took three of the legs, and
9 they're the ones that are sticking out of the vena cava. You
09:52:48 10 only see two of them because one is behind the other. So
11 there's three of them sticking out. So I took those three
12 legs and I allowed them to cut through the wall of the vena
13 cava and to protrude beyond the vena cava. And so by that
14 process I simulated how perforation would take place.

09:53:10 15 And as you can see, the perforation process also
16 leads to tilt because the filter is now unbalanced because
17 it's supported in different ways by the different sides of the
18 vena cava, and the consequence of that is that the filter will
19 tilt.

09:53:28 20 So perforation can lead to tilt, it almost always
21 leads to tilt, in my opinion, and tilt can lead to
22 perforation.

23 Q All right. Now, in this case, did Lisa Hyde's filter
24 perforate the vena cava?

09:53:45 25 A Yes. It's known that several of its struts perforated the

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09:53:50 1 wall of the vena cava.

2 Q And you said you did calculations that showed you under
3 what circumstances and under what -- that the G2, G2X, and
4 Eclipse would perforate the vena cava; is that correct?

09:54:03 5 A Well, what I did was that I established that when the --
6 when tilt occurs, for example, that the forces applied by the
7 arms and legs on the wall of the vena cava become different
8 from each other so that there's more thrust on one side of the
9 vena cava compared to the other, and that that process is
09:54:29 10 likely to cause the arms and the legs to then perforate
11 through the wall of the vena cava.

12 Q Now, did you look and review Bard's testing or analyses
13 along this line?

14 A I did.

09:54:44 15 Q And what is your opinion about Bard's analysis that
16 relates to perforation?

17 A Well, they didn't have any perforation tests. In other
18 words, they didn't simulate in any way, either by calculation
19 or by a bench test, the process by which limbs of the filter,
09:55:04 20 struts of the filter would cut through the wall of the vena
21 cava, and they have no measurement of the likelihood of that
22 occurring.

23 A point to make is that the higher the forces that
24 the filter applies to the wall of the vena cava, the more
09:55:23 25 likely the limbs are to cut through the wall of the vena cava.

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09:55:28 1 So if I take my paper clip and poke it gently against
2 my hand, I'm going to just hurt myself a little bit. But if I
3 press really hard, I can cut into my tissue. And so the
4 bigger the force, the more likely the perforation process is
09:55:51 5 to occur. And of course if the end is quite sharp, then that
6 makes the situation even more likely.

7 And what Bard should have done is to do some sort of
8 test that would identify how big those forces need to be to
9 get the struts of their filter to cut into the wall of the
09:56:09 10 vena cava. But they did no such test and did no such
11 investigation of that situation, even after they knew that the
12 Recovery filter was experiencing perforations of the vena
13 cava.

14 Q Thank you.

09:56:24 15 And had Bard done appropriate tests, do you have an
16 opinion whether Bard would have known or should have known
17 about perforation?

18 A Yes, that's correct.

19 Q And you say that there was knowledge even before the G2,
09:56:39 20 G2X, based upon the experience with the Recovery?

21 A That's correct.

22 Q And did your testing and analysis explain to you, give you
23 an explanation as to what happened to Lisa Hyde's filter?

24 A Yes. In my opinion, the design defects led to it
09:57:02 25 perforating the wall of the vena cava, and since the

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09:57:06 1 perforation process, which I can explain to you later,
2 increases the strains that the filter will experience, that
3 led to the strains on the filter being excessive while she
4 breathed, and that eventually broke an arm on the filter,
09:57:22 5 which migrated to her heart.

6 Q All right. Is this an appropriate time to talk about
7 perforation?

8 A Yes.

9 Q And I think you touched on it, but perforation is when the
09:57:32 10 filter penetrates through the walls of the vena cava.

11 A That's correct.

12 Q And can we take down this, or do you want the illustration
13 up?

14 A No, we can take down that because I'm going to do -- I'm
09:57:45 15 going to use some of the stuff on the desk to illustrate --

16 MS. HELM: Again, Your Honor, can we please proceed
17 in question answer format.

18 THE COURT: You need to lead the witness with
19 questions, Mr. O'Connor, not vice versa.

09:57:59 20 MR. O'CONNOR: I will.

21 BY MR. O'CONNOR:

22 Q So we've taken down that illustration. Now, you've
23 told -- I'd like you to tell us if you have an opinion
24 regarding the relationship between a limb of the filter
09:58:08 25 perforating a vena cava and how that results in fracture.

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09:58:12 1 A Yes, I can.

2 Q All right. Do you have an opinion?

3 A I have an opinion.

4 Q And what is it?

09:58:18 5 A The opinion is this: That when -- when a person who has a
6 filter breathes, as I indicated before, it causes the limbs of
7 the filter to be squeezed and unsqueezed many, many times.

8 And so I'm going to substitute a couple of pens for the
9 filter. So imagine that these two pens are limbs of the

09:58:54 10 filter. They look a bit like the legs but I want you to
11 imagine they're also representing the arms, which would be
12 more like this shape. But I don't have a bent pen so I can't
13 do that with pens.

14 So when you breathe in, the filter is forced to do
09:59:13 15 that. When you breathe out, it's forced to do that. And
16 since these bits down here are attached to the wall of the
17 vena cava, how much the vena cava contracts determines how
18 much the filter is being squeezed. Okay?

19 So just bear that in mind when I go on to my next
09:59:37 20 thing, which is a bit bigger, to make what I'm trying to
21 demonstrate easier to see.

22 So this is now representing one of the pens and it's
23 representing one of the limbs of the filter.

24 And the wall of the vena cava is down here. The cap
09:59:59 25 is up here holding the filter in a given position.

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10:00:05 1 And when I breathe in, the ruler, representing the
2 strut, is bent. When I breathe out, it bends back.

3 And a feature of this way that things happen is that
4 the strains up here are where they're biggest in the whole
10:00:29 5 setup, and I can make the strains bigger by having a bigger
6 contraction of the vena cava. Okay?

7 So this will do a bit of fatigue damage. This will
8 do a lot of fatigue damage. Okay?

9 So if the vena cava contracts a lot, it will do more
10:00:50 10 fatigue damage to the filter.

11 Now, imagine that this filter limb now perforates the
12 wall of the vena cava. So instead of the wall being down
13 here, the wall is up there. Okay?

14 Now, the wall of the vena cava is still moving by the
10:01:11 15 same amount. That small amount that I said may not do very
16 much damage. But watch the end of the ruler. It moves a lot
17 more than in that previous example. And so just the process
18 of perforation and the depth -- the displacements and
19 deformations and constraints that this imposes on the filter,
10:01:36 20 that elevates the level of strain.

21 And so once perforation has occurred, the fatigue
22 damage rate is much greater and the filter will then have less
23 time until it fractures.

24 Q Now, does that opinion and that demonstration apply to the
10:01:54 25 three, the G2, G2X, and Eclipse?

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10:01:56 1 A It applies to the Recovery, the G2, the G2X, and the
2 Eclipse.

3 Q And is that -- have you demonstrated the relationship
4 between perforation and ultimate fracture?

10:02:10 5 A Yes. What I did was I essentially did calculations that
6 simulate the process that I just illustrated, and I calculated
7 the strain levels that would occur in both a filter which is
8 not perforated and a filter which is perforated. And then I
9 compared the resulting strains with the data for Nitinol and I
10:02:36 10 found that a perforated filter will fail relatively --
11 relatively rapidly. Much less than ten years of breathing.

12 Q And, Dr. McMeeking, is there something about the Bard IVC
13 filter that, the design or how it's put together, that makes
14 it more prone to penetrating --

10:03:00 15 A Yes.

16 Q -- the IVC walls?

17 A Yes. The limbs are relatively thin and they therefore
18 apply what we call a high pressure, which is a version of
19 stress, the force through a certain area. They apply a
10:03:15 20 relatively high pressure to the wall of the vena cava, and
21 just like when I was trying to poke the paper clip through my
22 hand, the higher that pressure, the more likely or the more
23 probable is the perforation process. And in addition, the
24 tips of the arms are quite sharp and that aids the process by
10:03:41 25 which the ends of the arms can go through -- cut through the

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10:03:45 1 wall of the vena cava.

2 Q Now, earlier we talked about and you showed the jury the
3 cap on the filter.

4 A Yes.

10:03:54 5 Q And you gave us a demonstration before showing us the top
6 of the filter after it fatigued and how penetration or
7 perforation would affect fracture. Do you recall that?

8 A That's correct.

9 Q Is there anything about the cap, the design of the filter
10 and its cap, that Bard should have known would make its filter
11 more susceptible to fracture?

12 A Yes, there is.

13 Q What is that?

14 A It's the shape of the cap where the arms and legs come out
10:04:23 15 of the cap. And this is easiest to illustrate with a hand
16 drawing, although it wouldn't be very pretty because I'm not
17 much of an artist.

18 But the cap, a cross-section of the cap looks like
19 that. So the cap, it's a round cylinder with a cap on the
10:04:50 20 end. And the arms and legs come out of it. This is not
21 really to scale. But because there's 12 of these arms and
22 legs inserted into this cavity, but the arms and legs come out
23 like that, especially the arms, and you notice that where they
24 come out of the cap, the arms can be right up against this
10:05:17 25 corner, and the corner is a relatively sharp feature. And

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10:05:24 1 that sharp feature has the effect of raising the strains even
2 further from the levels which would be present if that sharp
3 edge was not there. That's what we call a strain
4 concentration. And so that's just a jargon word for the
10:05:44 5 strains are higher than perhaps they ought to be.

6 Q And was there something about the G2, the G2X, and even
7 the Eclipse that -- where the design of the cap contributed to
8 the fracture?

9 A Yes. Because when the arms interfere with the cap right
10:06:08 10 here, as -- remember these arms are moving back and forward
11 like that as the -- as you breathe as the filter is compressed
12 and expanded by breathing. And as that happens, the arms can
13 interfere with the cap, and that can generate the very high
14 strains that I mentioned just a minute ago, and when those
10:06:34 15 very high strains are generated, that can lead to rapid
16 fatigue damage and fracture of the filter in a relatively
17 short time.

18 That situation could have been guarded against by
19 having a gentler curve in the -- at the end of the cap where
10:06:57 20 the arms come out of the -- of the sheath so that the
21 situation would look more like that. That's a more benign
22 situation than the very sharp corner that the filters have.
23 And this, what we call breaking of the edge, or chamfering,
24 would be -- is very beneficial to controlling strain
10:07:22 25 concentrations. And every engineer who is taught about

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:07:25 1 designing against fatigue is told without any ambiguity that
2 they must guard against excessive strain concentrations. It's
3 one of the most important things to worry about in designing
4 against fatigue.

10:07:44 5 Q Now, you reviewed opinions by Bard's expert engineers; is
6 that correct?

7 A That's correct.

8 Q Did he do calculations that address the failure modes that
9 you addressed?

10:07:55 10 A Yes, he did.

11 Q And what is your -- do you have an opinion about the
12 appropriateness of his calculations?

13 A Well, in my opinion he -- in almost all cases he chooses
14 assumptions which are favorable to the ability of the filter
10:08:14 15 to survive. In other words, he chooses conditions that will
16 not impose worst-case conditions on the filter and, as a
17 consequence, his calculations tend to predict that the filter
18 will be perfectly safe.

19 Q And -- and those terms are just what you found in your
10:08:37 20 review of this case, and the work you've done in this case, is
21 that consistent with the reality of how these filters behaved?

22 A Well, yeah. What's observed in practice is that filters
23 do fail in the various ways that we've discussed.

24 Q Okay. And that's something that Bard should have known
10:09:01 25 had they done the appropriate test?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:09:03 1 A That's correct.

2 Q And Bard's own expert, had he done the appropriate test,
3 would have been able to explain why the filters have failed?

4 A That's correct.

10:09:15 5 Q Now, the design flaws that you talked about that pertain
6 to the failure modes include the conical design?

7 A Yes. The conical design is a basic defect of the design.

8 Q And what about the limbs?

9 A The limbs, as I mentioned, have this feature where they're
10 very thin and sharp, and that's a design defect of the filter.

11 Q Now, in your work in this case, did you apply your
12 findings, including your opinions about Bard's inadequate
13 testing and the defective design to the case of Lisa Hyde?

14 A I did.

10:10:02 15 Q And what are your findings in terms of just what your
16 findings showed in your work and can you explain just how her
17 filter failed.

18 A Well, her filter failed because it -- its failures were
19 associated with perforation of limbs through the wall of the
10:10:27 20 vena cava and it failed by a fatigue fracture where one of the
21 arms broke near the cap here in this area, and that failure
22 was caused by fatigue, as I said, and it is more probable than
23 not that it was associated with perforation of that limb
24 through the wall of the vena cava.

10:10:57 25 Q And is that an opinion that you hold to a reasonable

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:11:01 1 degree of engineering certainty?

2 A It is.

3 Q And that the defects and design of the inadequate testing
4 were -- resulted in the failures that Lisa Hyde's filter
10:11:15 5 experienced?

6 A That's correct.

7 Q Now, have you looked at the Simon Nitinol filter in your
8 work?

9 A I have.

10:11:22 10 Q And do you have one with you?

11 A I have one with me.

12 Q Will you show -- can you pull that out?

13 A Yes, I can.

14 Q And do you have an opinion about the Simon Nitinol filter?

10:11:34 15 A Yes. My opinion about the Simon Nitinol filter from an
16 engineering perspective is that it is a safer design. It is a
17 safer filter.

18 Q Now, you know that was a permanent filter; correct?

19 A I know it's a permanent filter.

10:11:53 20 Q And by the way, the G2, the G2X, and the Eclipse, were
21 those all designed and promoted by Bard to be permanent
22 filters?

23 A Yes. The G2, the G2X, and the Eclipse are -- they're
24 marketed and represented as filters that can be left in the
10:12:12 25 patient on a permanent basis. In fact, the Recovery filter

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10:12:17 1 was introduced as a permanent filter and the G2 was introduced
2 as a permanent filter. It was only cleared for retrieval
3 later. So as their first manifestation, these filters were
4 permanent filters.

10:12:36 5 Q And in the time that the G2, the G2X, and the Eclipse were
6 on the market, did Bard do anything to those filters to change
7 the design to make them less prone to the failures you
8 discussed during -- with those filters?

9 A Sorry, could you ask the question again?

10:12:53 10 Q Yeah. Did Bard do anything to those filter to change the
11 design?

12 A Are you asking me about the Recovery or the G2?

13 Q G2 and the G2X, yeah.

14 A So the G2 and the G2X, the only difference was the
10:13:06 15 addition of a retrieval hook and a small modification of
16 the -- of the -- of the cap.

17 Q I think my question threw you off.

18 Let's just go back. You started on the Simon Nitinol
19 and you have opinions about that and why that's a safer
10:13:21 20 filter. So if you could walk us through your opinion as to
21 what made the Simon Nitinol filter safer than the G2, G2X, and
22 Simon Nitinol.

23 A Okay.

24 So the Simon, the filter is a much stiffer filter.

10:13:38 25 So if I try and squeeze these -- well, let me describe it,

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:13:42 1 first of all.

2 It has legs, which I think you can see down at the
3 bottom on the left. And it has a basket at the top which is
4 formed of fairly complicated loops of metal. You can look at
10:13:59 5 it from the top to see them.

6 It has two -- two -- it has a cap at the top, just
7 like the other filters, and it has another sheath in the
8 middle, which you can see when I hold the filter like that.
9 You can see there's a slightly thicker feature which is
10:14:27 10 between the basket and the legs. And so that's a sheath that
11 holds all the wires together, just as the sheath at the top,
12 the cap, holds all the wires together. Okay?

13 Now, a feature of the design of the Simon Nitinol
14 filter is that the -- it's shape makes it a much stiffer
10:14:54 15 filter. So if I try and squeeze the filter, I feel much more
16 resistance when I try to squeeze it than I experience when I
17 squeeze the arms and legs, even several of them at the same
18 time. When I squeeze the arms of the Eclipse filter.

19 Now, the good thing about that is it fixes the filter
10:15:28 20 much more firmly in the vena cava. And, as a result, it is
21 less, in my opinion from an engineering assessment, less prone
22 to migration, less prone to moving either upwards or downwards
23 in the vena cava.

24 In addition, it has the feature that even if it might
10:15:55 25 tilt, the legs of the filter are sort of disconnected in a

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10:16:01 1 tilting sense from the basket or the arms of the filter. So
2 you see that let's say the arms at the top here want to tilt,
3 they can tilt without the legs having to go with them.

4 Whereas the -- whereas the shape that I'm showing you
10:16:30 5 now, if the arms tilt, if the arms want to tilt, the legs have
6 to go with them. And if the legs want to tilt, the arms have
7 to go with them because they're all gathered together in a
8 single cap.

9 But the -- but the sheath in the middle allows -- and
10:16:52 10 the way that the wires are all gathered together allows the
11 tilting process to be decoupled. The basket can tilt and the
12 legs don't or the legs can tilt and the basket does not.

13 So tilting is not such a serious problem, in my
14 opinion from an engineering perspective, in the Simon Nitinol
10:17:17 15 filter.

16 Q All right and -- go ahead.

17 A But --

18 Q I wanted to ask you about fracture from the arms.

19 A Yes. That's the next thing to consider. Which is that
10:17:27 20 the configuration of the basket is such that the basket is
21 much less likely to perforate through the wall of the vena
22 cava. The reason is, if I look at it from the top, there's a
23 very large length of the wires which will be touching the wall
24 of the vena cava. And because of that, the force, the
10:17:56 25 pressure which the wires are applying to the wall of the vena

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10:18:01 1 cava, are significantly less in the Simon Nitinol filter than
2 in the G2 family of filters. I pointed out that if the
3 pressure applied is less, that the likelihood of cutting
4 through the tissue is less. And so these wires are much less
10:18:27 5 likely to perforate through the wall of the vena cava.

6 Since perforation is one of the biggest actors in
7 terms of promoting the strains that will lead to fatigue
8 failure, having a filter that doesn't perforate through the
9 wall of the vena cava is a major advantage. And, therefore,
10:18:52 10 in my opinion from an engineering perspective, this is a much
11 better filter in terms of trying to control or controlling the
12 likelihood of fatigue fracture of the arms at the top of the
13 filter. These petal-like features which are in the basket at
14 the top of the filter.

10:19:16 15 Q Is that an opinion you hold to a reasonable degree of
16 engineering probability?

17 A I do.

18 Q All right. I want to quickly go through testing that you
19 reviewed.

10:19:25 20 A Sorry. Ask me that again, please.

21 Q I want to go through testing of each of the filters.

22 A Okay.

23 Q Did you review and report in this case on the Recovery
24 testing?

10:19:35 25 A I did.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:19:35 1 Q And did you report your opinions?

2 A I did.

3 Q What are your opinions on testing of the Recovery?

4 A My opinion on testing the Recovery is that the testing was
10:19:44 5 inadequate because several tests that should have been carried
6 out were not carried out, and some tests that were carried out
7 were not carried out in an adequate manner, in a proper
8 manner.

9 Q In -- in your -- when you arrived at your opinions and you
10:20:02 10 reported your opinions, did you talk about the Recovery filter
11 arm fatigue testing?

12 A I did.

13 Q And what is the opinion you had about that?

14 A My opinion is that that test is not one that tells us very
10:20:16 15 much about the fatigue resistance of the Recovery or any of
16 the other G2 family of filters.

17 Q Why?

18 A Because it's a very special test, and I can describe it in
19 the following way, which is that what Bard did was they took a
10:20:37 20 filter which would look originally like this one and they cut
21 the legs off. So now the filter just has these arms, these
22 bent struts that are the arms of the filter.

23 They then took that filter and they put it in a
24 machine to test it and they did it in such a way that the
10:21:06 25 filter was held, if you like, with its arms out like this and

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10:21:12 1 it was -- it was gripped here underneath the cap. And then a
2 shaft -- it was gripped at the top of the cap. And a shaft
3 was brought up from the bottom to force the arms to go up, and
4 they were pushed up by one centimeter. Okay?

10:21:31 5 And that test was carried out until three of the arms
6 broke. And that was a test of the process of fatigue that the
7 arms would experience if such large deflections of them was
8 imposed.

9 Q And, again, was that called the Recovery filter arm
10:21:55 10 fatigue test?

11 A That's correct.

12 Q And did you actually review the test?

13 A I did.

14 Q And what did you review about the test that you felt was
10:22:07 15 significant to tell the jury?

16 A Well, I -- I found this test didn't tell anyone very much.
17 It told you what would happen if you imposed that kind of
18 deformation on the filter, which is a special situation which
19 it could occur if -- for example, if an arm got trapped in a
10:22:28 20 renal vein which is off to the side of the vena cava, so it's
21 a special circumstance, and the test was designed to identify
22 what might happen if that occurred. And what was identified
23 in the test is that the Recovery filter, which is the original
24 of the series of filters that we're discussing, it looks
10:22:55 25 slightly different from this, it would last an average of

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:23:00 1 about 60 cycles before three of its arms broke. Now, that, of
2 course, is alarming by itself because that's not a very big
3 number of cycles of loading that the filter would be going
4 through.

10:23:15 5 Q Did you see documentation where Bard actually recorded
6 that?

7 A Yes.

8 Q In what document?

9 A It's -- it's a test report of the -- of the -- of the
10:23:26 10 fatigue test.

11 Q Does it start out with handwritten notes from an engineer?

12 A Yes. There's a -- there's items which seem to be an
13 extract from a lab book that I reviewed that describe the
14 process and some of the results of the test.

10:23:45 15 Q All right. I'd like to show you Exhibit 2028.

16 I'm sorry. Exhibit -- I said that wrong. I
17 apologize. Exhibit 876.

18 MR. O'CONNOR: Sorry, Felice.

19 BY MR. O'CONNOR:

10:24:17 20 Q I'm showing you Exhibit 876. Is this the document that
21 you reviewed in your work?

22 A Yes. That's correct.

23 Q And is this a document that you reviewed to report the
24 opinions in the course of this case?

10:24:27 25 A That's correct.

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10:24:29 1 Q And the opinions that you talked about here today?

2 A That's correct.

3 MR. O'CONNOR: And if we could turn to page 17,
4 please, Felice.

10:24:41 5 BY MR. O'CONNOR:

6 Q When you were talking earlier about the numbers of cycles
7 that Bard used and why that was inadequate, do you recall that
8 testimony?

9 A That's correct. Yes.

10:24:51 10 Q Is that illustrated on this page of the testing document?

11 A That is.

12 MR. O'CONNOR: And at this time I would move for
13 admission of 876, Your Honor.

14 MS. HELM: No objection, Your Honor.

10:25:02 15 THE COURT: Admitted.

16 (Exhibit 876 admitted.)

17 MR. O'CONNOR: And may we display page 17 to the
18 jury?

19 THE COURT: Yes.

10:25:09 20 BY MR. O'CONNOR:

21 Q Dr. McMeeking, if you could, quickly tell the jury what
22 this shows that supports the opinion you have about Bard's
23 inadequate testing.

24 A Well, it shows the result that I mentioned a minute ago,
10:25:24 25 which is that the Recovery filter, which is the one that's

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:25:29 1 described as current RF, it failed on average after 57 of
2 these cycles of motion imposed on the arm.

3 The -- so the number is actually 57. The modified
4 Recovery filter is one that -- you can't see this anymore.

10:25:55 5 The modified Recovery is the G2, and it's just the same shape
6 as this one. And you can see that it survives 628 cycles.
7 And so in this test, the G2 did perform significantly better
8 and lasted at about 11 times longer than the original Recovery
9 filter.

10:26:21 10 Q Was that adequate in your mind, though?

11 A Well, as I said, the fact of the Recovery would fail after
12 57 cycles -- I said 60 -- but after 57 cycles is alarming by
13 itself. And failing after 628 cycles is still a very low
14 number in terms of the number of loadings that the filter
10:26:42 15 could experience if it got into the situation where this was
16 the loading which the filter would experience.

17 Q All right. Now, let's --

18 MR. O'CONNOR: We can take this down.

19 BY MR. O'CONNOR:

10:26:58 20 Q Let's talk about G2 testing. Did you review design
21 activities and tests for the G2 --

22 A I did.

23 Q -- and G2X?

24 And do you have an opinion whether they were
10:27:06 25 reasonable?

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10:27:07 1 A My opinion is that they were not reasonable and the
2 testing was inadequate.

3 Q What did Bard actually do to redesign the G2? You just
4 mentioned it quickly, but just to bring us back to that.

10:27:20 5 A So -- may I have the Elmo back on.

6 So the redesign of the Recovery to the G2 had some
7 of -- had the following features.

8 They made the stance wider. In other words, they
9 moved the feet and -- they moved the feet further apart from
10:27:47 10 each other. They lengthened the arms and -- so that the
11 original Recovery had shorter arms than the ones that you can
12 see the bent arms on this filter.

13 They added a wrist at the end of the filter, which
14 was a flat segment that rested against the wall of the vena
10:28:11 15 cava in many circumstances.

16 And they made the curve of the wires coming out of
17 the cap gentler. The ones that are the arms. And so I'll
18 draw a picture of that to make it clearer. So in the
19 Recovery, the arms more or less look like that, where they
10:28:38 20 come out of the cap. But in the G2 the arms came out with a
21 gentler curve, like that.

22 And so those were the main changes that took us from
23 the Recovery to the G2.

24 And, of course, the lengthening of the arms also
10:29:00 25 widened the stance of the filter because the hands on the arms

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10:29:05 1 were now further apart.

2 Q Now, let me ask you a question. Did you see any evidence
3 in this case that Bard did any type of a root cause analysis
4 of what -- why the Recovery was failing?

10:29:17 5 A They failed to complete a successful root cause analysis
6 of why the Recovery was failing.

7 Q And what is a root cause analysis from an engineering
8 perspective?

9 A Well, a root cause analysis is an investigation to
10 determine the cause of a failure. And so you investigate the
11 problems that the filter will experience. You investigate the
12 failure modes and you carry out further calculations, if
13 necessary. You carry out further bench tests, if necessary,
14 to confirm or otherwise that you have found the real reason
10:29:57 15 why a failure is taking place.

16 Q We're getting ready for a break. But two questions real
17 quick.

18 Is root cause analysis necessary to learn about
19 design defects?

10:30:08 20 A Yes. If a component, a device or anything, a structure,
21 is failing, it is essential engineering design practice to
22 carry out a root cause analysis for why that failure is
23 occurring and to use the outcome of that root cause analysis
24 to make design changes that would eliminate or reduce as much
10:30:35 25 as possible the failure modes which are being experienced.

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10:30:39 1 Q So the changes you showed us in the G2, were those based
2 upon any type of root cause analysis?

3 A No, they were not. Because since they did not
4 successfully complete a root cause analysis, they had no idea
10:30:52 5 why the Recovery was failing, and therefore the design changes
6 they made to move to the G2 were simply shots in the dark in
7 terms of how the design might be improved.

8 Q All right. Thank you.

9 THE COURT: All right. We're going to take a break
10:31:08 10 at this point, ladies and gentlemen. We will break until 13
11 minutes to the hour.

12 We'll excuse the jury at this time.

13 (The jury exited the courtroom at 10:31.)

14 THE COURT: Counsel, for your information, because of
10:31:41 15 a meeting I have at lunch, our lunch break is going to go from
16 noon until 1:15.

17 All right. We'll see you in 15 minutes.

18 (Recess taken from 10:32 to 10:47. Proceedings resumed
19 in open court with the jury present.)

10:47:58 20 THE COURT: Thank you. Please be seated.

21 You may proceed, Mr. O'Connor.

22 MR. O'CONNOR: Thank you, Your Honor.

23 BY MR. O'CONNOR:

24 Q All right, Dr. McMeeking, before we went to break you
10:48:06 25 talked about the failure of Bard to do a root cause analysis

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1 on the Recovery and you told us why that would be important if
2 you were going to design or redesign a filter in a way to
3 eliminate the design defects that resulted in the failure
4 modes that the Recovery experienced; correct?

5 A That's correct.

6 Q And from what you told us is that the G2, despite the
7 design's changes, were they based on any type of root cause
8 analysis by Bard?

9 A No, they were not.

10 Q Now let's move on to the G2 and talk about your opinions
11 regarding design activities and testing for the G2 filter.
12 And we talked about that opinion. Does that also applied to
13 the G2X and Eclipse?

14 A It does. They do.

15 Q And so when I talk about that, the jury can infer that
16 those -- your opinions on those should apply across the board
17 with those two other filters?

18 A That's correct.

19 Q And when we talk about design activities and tests for the
20 G2, do you have an opinion whether Bard's were reasonable?

21 A My opinion is they were not reasonable.

22 Q And you told us what Bard did to redesign the filter, the
23 G2. But, again, had they done a root cause, as you had told
24 us they should have, Bard that is, what should have been
25 looked at?

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10:49:45 1 A They should have looked at the interactions among the
2 failure modes. For example, perforation possibly leading to
3 fracture; tilt leading to perforation; perforation leading to
4 tilt, and they should have investigated more thoroughly the
10:50:08 5 environment and conditions that the filter would be
6 experiencing in the human patients. And they should also
7 have -- they should have considered their failure modes more
8 thoroughly in terms of those that they were anticipating to be
9 problems.

10:50:28 10 Q Let me ask you this: When Bard was developing the G2, did
11 Bard test for known problems with Recovery such as tilt?
12 A No, they did not.

13 Q And you told us the Recovery was known by Bard to have
14 been perforating.

10:50:46 15 A Correct.

16 Q Did Bard conduct any tests before the G2 for perforation?
17 A No, they did not.

18 Q What about a flat plate fatigue test?
19 A They did not carry out a flat plate fatigue test on the G2
10:51:04 20 at all. The flat plate fatigue test is the equivalent of the
21 test I described where the filter is put in a tube and the
22 tube is squeezed. The flat plate fatigue test is one where
23 something similar is done except you're looking specifically
24 at flat plates that are squeezing the filter through the tube.

10:51:28 25 Q I just realized something.

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10:51:33 1 There is a document entitled Flat Plate Fatigue and
2 Corrosion Examination for the G2 Express Filter; is that
3 correct?

4 A Yes. That's for the G2 Express but not the G2.

10:51:44 5 Q All right. What was done in that test?

6 A In the case of the G2 Express, the -- the filter was,
7 again, placed in a tube and the tube squeezed between flat
8 plates, and the filter was tested for 29 million cycles until
9 one of them failed by fatigue.

10:52:12 10 Q All right. Was that an adequate test?

11 A No, it was not an adequate test because it was not done
12 under worst-case conditions and it did not run for the
13 80 million cycles that would represent ten years of breathing.

14 MR. O'CONNOR: I need to have a discussion real quick
10:52:33 15 with my team, Your Honor.

16 (Counsel confer.)

17 BY MR. O'CONNOR:

18 Q Before the G2 came out, did Bard test for caudal
19 migration?

10:52:56 20 A No.

21 Q What about the finite element analyses that were done with
22 respect to the G2 after the Recovery?

23 A The finite element analysis was inadequate just as that
24 that was done for the Recovery was inadequate. It failed to
10:53:11 25 address worst-case conditions, and I also found a lot of

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:53:15 1 inconsistencies in the results.

2 Q In what way?

3 A Well, they would compute results for strain and I would
4 compare them with my own predictions of the strains in exactly
10:53:29 5 the same circumstances, and the results that Bard's engineers
6 were getting were different from the ones that I obtained.

7 Q There was a saluting arm test that you discussed.

8 A That's correct.

9 Q What is that?

10:53:46 10 A That's the test that I described where the arms are forced
11 to move up by a certain distance until three of the arms break
12 on the filter.

13 Q And when the -- whatever Bard did with respect to the G2,
14 did they do anything that looked into the worst case?

10:54:16 15 A No. So when they carried out tests and calculations, none
16 of the conditions which they imposed were worst-case
17 conditions. And, in fact, they did not even carry out
18 breathing fatigue test on the G2, but, instead, relied on the
19 Recovery filter results to claim that the G2 filter had
10:54:47 20 adequate fatigue resistance in terms of ten years of
21 breathing.

22 Q So are you saying that Bard did not do a new test for the
23 G2 as it related to the breathing?

24 A That's correct.

10:54:59 25 Q And are you saying that Bard relied on its findings from

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:55:01 1 the Recovery?

2 A Yes. What they did was they took the results from
3 Recovery test, which itself was not adequate because it had
4 not lasted the ten years of breathing, and they did a finite
10:55:16 5 element calculation.

6 And the finite element calculation that they did was
7 actually erroneous because it had nothing to do with cycling
8 the filter by breathing, it was a calculation that was only
9 concerned with implanting the filter into the IVC, into the
10:55:35 10 inferior vena cava, and they used the results of the finite
11 element calculation which were irrelevant to fatigue, to make
12 the deduction that the G2 filter would have adequate fatigue
13 resistance when it was to be tested in breathing for ten
14 years. In other words, 80 million cycles. And out of that
10:56:00 15 process decided not to do any test on -- a breathing fatigue
16 test of the G2 filter.

17 Q Are you familiar and did you report and arrive at an
18 opinion on Bard's claim that the G2 is 12 times more fracture
19 resistant than the Recovery?

10:56:20 20 A Yes, I'm aware of that claim.

21 Q And is that a result that Bard took from the saluting arm
22 test?

23 A Yes. That's correct.

24 As you may recall, when we were looking at the
10:56:34 25 results of what was called the arm fatigue test, and is also

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1 called the saluting arm test, the G2 filter survived
2 approximately 600 cycles of loading before three arms failed,
3 whereas the Recovery survived about 60. About 50 cycles. And
4 that's a ratio of approximately 12, although it's more like
5 11. And Bard then used that information to claim that the G2
6 filter was 12 times more fatigue resistant than the Recovery.

7 Q Let me show you Exhibit 876.

8 MR. O'CONNOR: Felice, can you get that up.

9 Is that the right one, Mark? 876?

10 Felice, can you get to that page we showed earlier,
11 the chart.

12 BY MR. O'CONNOR:

13 Q Now, this was shown to the jury early in the case. Does
14 this support the claim that the G2 is 12 times more fracture
15 resistant than the Recovery?

16 A Well, as I said, the ratio is more like 11. But there are
17 numbers that go where 12 that have been in document as well.

18 But what this comparison shows is simply if you do
19 this to the filter, the G2, it will last 12 times longer than
20 the Recovery.

21 These results say little more than that in terms of
22 the overall fatigue resistance of the filter because it says
23 nothing about how the filter will survive, or not, under ten
24 years of breathing, and it says nothing about how long the
25 filter can last under coughing or Valsalva or other

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

10:58:53 1 deformations that the filter will be subjected to.

2 Q So that test you just showed, which is the test results
3 that Bard has displayed --

4 MR. O'CONNOR: May we show this to the jury,
10:59:05 5 Your Honor?

6 THE COURT: You may.

7 MR. O'CONNOR: Please display.

8 BY MR. O'CONNOR:

9 Q So Bard used the results from that saluting arm test to
10:59:16 10 represent it as a -- as a respiratory test?

11 A They did not represent it as a respiratory test, they
12 simply -- they simply made statements that the G2 filter is 12
13 times more fracture fatigue resistant than the Recovery.

14 Q And is it your opinion in this case that that test does
10:59:37 15 not appropriately show or support that statement?

16 A It does not show or support that statement because this
17 test has nothing to do with a respiration fatigue test, a
18 breathing fatigue test. Has nothing to do with a test that
19 would investigate the effect of Valsalva and coughing.

10:59:56 20 Q How often -- would you anticipate that the filter would
21 get into a saluting position very often while in the vena
22 cava?

23 A Well, the Recovery filter was known to get into that
24 situation by one of its arms getting into a renal vein. But
11:00:14 25 the lengthening of the arms of the G2 filter was one of the

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1 steps, although it was a shot in the dark, it was designed to
2 try and get rid of that problem. And it seems to have worked
3 because as far as I know there have been few reports of arms
4 of the G2 family being trapped in the renal vein.

11:00:36 5 Q So did this test prove general fracture resistance?

6 A No, it did not.

7 Q Did this test prove that the G2 is generally 12 times more
8 fracture resistant than the Recovery?

9 A No, it did not.

11:00:47 10 Q And I think you've told us that there are tests that can
11 prove fracture resistance.

12 A Yes. The flat plate fatigue test or the test of the
13 filter in a tube to simulate breathing conditions under
14 worst-case conditions is the sort of test that would be able

11:01:05 15 to establish the true difference in fatigue resistance of
16 these types of filters.

17 Q And did Bard conduct any tests to determine whether the G2
18 is generally more fracture resistant than the Recovery?

19 A They carried out no bench test of the fatigue performance
11:01:23 20 of the filter under breathing.

21 Q Now, did you see anything from Bard's engineering that
22 discussed the saluting arm fatigue test in your report?

23 A I did.

24 Q And did you review an e-mail and discuss it in your
11:01:45 25 opinions?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:01:46 1 A I did.

2 Q And would you tell us what you reviewed.

3 A I reviewed an e-mail from a Bard engineer by the name of
4 Micky Graves.

11:01:54 5 Q And what was it about that e-mail that assisted you in
6 formulating opinions about the testing that Bard conducted?

7 A The e-mail indicates Bard decided when assessing a test
8 they were thinking of carrying out, they made the assessment
9 that the test would actually give them problems in the sense
11:02:19 10 that the results of the test would show that the G2 filter was
11 not adequately resistant to fatigue, and because of that they
12 decided not to carry out the test.

13 Q All right.

14 MR. O'CONNOR: Let's show Dr. McMeeking Exhibit 1295,
11:02:36 15 please.

16 BY MR. O'CONNOR:

17 Q Dr. McMeeking, this the e-mail you reported on in stating
18 your opinions?

19 A That's correct.

11:02:50 20 Q And was this the basis of the opinions you've arrived at
21 in this case?

22 A It was one of the bases, yes.

23 MR. O'CONNOR: Move for admission of 1295.

24 MS. HELM: No objection, Your Honor.

11:03:00 25 THE COURT: Admitted.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

09:25:03 1 (Exhibit 1295 admitted.)

2 MR. O'CONNOR: May we display to the jury?

3 THE COURT: Yes.

4 BY MR. O'CONNOR:

11:03:06 5 Q So, Dr. McMeeking, this is an e-mail that we're looking at
6 from Micky Graves. Is it your understanding he was an
7 engineer?

8 A That's -- that's correct. I -- I didn't read quickly
9 enough his actual title, but he was associated with the
11:03:23 10 engineering staff of Bard.

11 Q All right. And what test is he --

12 MR. O'CONNOR: You can enlarge it, please.

13 BY MR. O'CONNOR:

14 Q What test is Mr. Graves talking about?

11:03:40 15 A He's talking about the saluting arm test.

16 Q The one that you just talked about?

17 A That's correct, yes.

18 Q And did he suggest that Bard should have run a different
19 type of test?

11:03:59 20 A Well, what he was suggesting is that there was a need to
21 run finite element analysis of the test. So that would go in
22 parallel with the saluting arm test that was done as a bench
23 test. And the question that is being raised is what would be
24 the results of those finite element analysis.

11:04:21 25 The conclusion that is being indicated is that those

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1 associated with that calculation were concerned or thought it
2 would end up outside of what is called the acceptable range of
3 the fatigue evaluation and therefore it would show that the
4 filter was prone to fatigue failures.

5 Q So the tests that you suggested Bard should have done were
6 not done.

7 A Correct.

8 Q And the e-mail that you have just talked about is an
9 e-mail that suggests that Bard was afraid of the results.

10 A That's correct.

11 Q And -- and they -- and Bard never did do that test?

12 A They never carried out that calculation. At least I've
13 not seen any report or results that concern that calculation.

14 Q So as of March 23, 2006, a member of Bard said, "We
15 settled on the arm bend fatigue test to give us an answer that
16 we are now 12 times more fracture resistant under specific
17 loading conditions," and he asks "The bigger question is, is
18 12 times more resistant enough? Now we are stuck answering
19 the same question a year later to even consider the trimming
20 of the wrist option."

21 A Yes.

22 Q And the test that Mr. Graves suggested should be run, from
23 your work in the case did you ever see evidence it was run?

24 A I've not seen any evidence that that calculation and test
25 was carried out.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:05:58 1 Q Thank you.

2 MR. O'CONNOR: We can take that down.

3 BY MR. O'CONNOR:

4 Q And what we just saw about the 12 times greater
11:06:09 5 representation by Bard and failure to do a test that would
6 have been more appropriate, does that conduct comply with
7 either safe or reliable design standards?

8 A No, it does not.

9 Q Now, you did review design activities and test activities
11:06:31 10 for the G2 Express?

11 A I did.

12 Q And that's the filter that had the additional hook on top;
13 correct?

14 A That's correct.

11:06:46 15 Q And were there any design changes to the G2X that would
16 have affected tilt, perforation, migration, or fracture?

17 A The -- as I mentioned, the cap had a slight modification
18 to the -- to -- so the G2 Express had a slight modification to
19 the cap, and it may have made a small difference to the
11:07:10 20 fatigue performance of the filter because it made the sharp
21 corner at the end of the sheath slightly gentler. But the
22 change was so small that, in my judgment, that would not make
23 sufficient difference to the fatigue performance of the filter
24 because the strains it was experiencing were so high that were
11:07:36 25 causing the fatigue damage that this small improvement to

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:07:39 1 the -- to the chamfer was not adequate in terms of addressing
2 that problem.

3 Q So for the G2X, was there a tilt test?

4 A There was no tilt test.

11:07:51 5 Q A test for perforation?

6 A There was no perforation test.

7 Q A test for caudal migration?

8 A There was no caudal migration test.

9 Q What about respiratory fatigue, did they test for that?

11:08:05 10 A Again, they didn't do a bench test for respiratory
11 fatigue. They did not carry out that test and, again,
12 justified not doing the test by pointing back to the Recovery
13 and the inadequate test that had been done for respiratory
14 fatigue in the case of the Recovery.

11:08:26 15 Q And even after question by its own engineers, Bard didn't
16 bother to do anything else?

17 A That's correct.

18 Q What about the finite element analysis that was done for
19 the G2X, was that adequate?

11:08:39 20 A The finite element analysis was inadequate as well.

21 Q Again, that saluting arm test didn't really prove
22 anything, did it?

23 A That's correct. Saluting arm test didn't tell us much
24 about the filter other than what happens when the arms are
11:08:52 25 caused to go through this motion.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:08:58 1 Q Which is something that Bard should have anticipated would
2 not apply to the G2?

3 A That's correct.

4 Q Now, the Eclipse, did you review Bard's design activities
11:09:08 5 for the Eclipse?

6 A I did.

7 Q Was there a change to the Eclipse?

8 A The Eclipse is the same shape and size and so on as the
9 G2X. The change that brought the Eclipse into the line of
11:09:33 10 filters was that the surface of the wires was electropolished.

11 Q Other than that, was the design identical to the G2 and
12 the G2X?

13 A That's correct.

14 Q And did electropolishing on the Eclipse, did that have any
11:09:53 15 impact on problems that Bard had with either the Recovery or
16 the G2?

17 A Well, it had no impact on perforation, it had no impact on
18 tilt, and it had no impact on caudal migration.

19 The purpose of electropolishing is to make the
11:10:13 20 surface slightly smoother. It's an electrical and chemical
21 process that removes small amounts of the surface of the
22 material and it's used for the purpose of improving the
23 fatigue life and the fatigue performance of components and
24 devices.

11:10:32 25 However, the situation in terms of the strains that

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:10:37 1 the filter was experiencing were -- are so severe that the
2 small improvement that would be associated with
3 electropolishing would make little difference. And so from
4 that perspective, the change that was made did not have any
11:10:54 5 significant or even worthwhile effect on the fracture and
6 fatigue resistance of the filter.

7 Q Well, earlier when you talked to us about perforation and
8 how the interaction through the vena cava shortens the
9 distance of the remaining filter limit and the cap -- do you
11:11:15 10 recall that?

11 A Yes.

12 Q And how that would affect stress and strains.

13 A Yes.

14 Q Did that same design flaw apply to the Eclipse?

11:11:22 15 A Yes. Yes, it did.

16 Q So did Bard do anything to the design of Eclipse that
17 would reduce or eliminate the root cause of perforation and
18 fracture?

19 A No, they did not.

11:11:43 20 Q And did you do calculations on each of those filters'
21 finite element analysis?

22 A I did calculations that were for the Recovery and the G2
23 filter, and the calculations I did for the G2 filter were
24 equally valid for the G2X and the Eclipse.

11:12:03 25 Q And the analysis you did on the Eclipse, does that show

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:12:06 1 any major difference?

2 A The results for the Eclipse in terms of the strains being
3 experienced were exactly the same as the strains being
4 experienced in the G2. And since those strains were
11:12:23 5 sufficiently high to cause early fatigue failures and
6 fractures of the filter and since the electropolishing did not
7 improve the fatigue resistance of the material enough, the
8 results of my calculations show that the Eclipse would be
9 subject to the fatigue and fractures that I -- that I
11:12:50 10 identified were a problem with the Recovery, with the G2, and
11 later with the G2 Express.

12 Q Yesterday another doctor came in and testified and he
13 talked about and we showed and looked at G2, G2X, fracture
14 analysis. Have you seen that document?

11:13:08 15 A I think -- yes, I have seen it.

16 Q But in terms of the G2, the G2X fracturing, you're aware
17 that was going on; right?

18 A Yes.

19 Q Did Bard ever do a root cause analysis before developing
11:13:24 20 the Eclipse and even releasing it to the market to find out
21 what it was about the G2 or G2X that was resulting in
22 fracture?

23 A No, they did not.

24 Q In fact, they didn't do one as far as going all the way
11:13:39 25 back to the Recovery.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:13:40 1 A That's correct. They didn't do a root cause analysis to
2 identify why the Recovery was failing. They didn't do one to
3 identify why the G2 was failing. They did not do one to
4 identify why the G2X was failing.

11:13:52 5 Q And is it your opinion for the Eclipse that Bard failed to
6 thoroughly test that filter as well?

7 A That's correct.

8 Q So was there any tilt test?

9 A There was no tilt test undertaken for those filters.

11:14:05 10 Q Was there any perforation test?

11 A There was no perforation test.

12 Q Was there any test for caudal migration?

13 A There was no caudal migration test.

14 Q All Bard did was electropolish and hope that might make a
11:14:16 15 change?

16 A That's correct.

17 MS. HELM: Object to the form. Leading.

18 THE COURT: Sustained.

19 Re-ask the question, pleas.

11:14:21 20 BY MR. O'CONNOR:

21 Q Did electropolishing make any difference?

22 A It did not make a sufficient difference.

23 Q And was there any respiratory fatigue test for breathing
24 done on the Eclipse?

11:14:33 25 A There was no respiratory fatigue test done on the Eclipse.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:14:36 1 Q So when we look at the G2, G2X, and the Eclipse, was there
2 anything about any design change that addressed the failure
3 modes of migration, tilt, fracture, perforation that Bard had
4 seen in the Recovery?

11:14:49 5 A There was nothing in what they did.

6 Q Did Bard ever use the saluting arm test again for the
7 Eclipse?

8 A Yes. They cut it out for the Eclipse and for the G2X.

9 Q Did you review what they did for the Eclipse?

11:15:08 10 A I did.

11 Q And for the G2?

12 A I did.

13 Q Did the tests get any better?

14 A No. It was still not a good test. It didn't tell much
11:15:16 15 about the filter.

16 Q And in your opinions -- for the basis of your opinions,
17 had you reviewed those tests and those test results from Bard?

18 A Sorry, could you ask the question again.

19 Q When you were formulating your opinions and reporting your
11:15:27 20 opinions, had you reviewed those tests?

21 A I did. I have.

22 Q And did you report your opinions of those tests in the
23 opinions that you gave in this case?

24 A I did.

11:15:37 25 Q And I'd like to show you now Exhibit 5385.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:15:50 1 Have you seen this document before?

2 A I have.

3 Q What's it entitled?

4 A It's entitled The G2 Express Filter Arm Fatigue
11:16:01 5 Comparison.

6 MR. O'CONNOR: And let's go to page 13, please,
7 Felice.

8 BY MR. O'CONNOR:

9 Q And do you recognize this page of the test?

11:16:12 10 A I do.

11 Q And what is represented here? Not the conclusions, just
12 tell us what it is.

13 A It's a page showing the results of the test.

14 Q And when you reported your opinions that this test was
11:16:24 15 inadequate, did you review this page?

16 A I did.

17 MR. O'CONNOR: And at this time I would move
18 Exhibit 5385 into evidence.

19 MS. HELM: No objection.

11:16:33 20 THE COURT: Admitted.

21 (Exhibit 5385 admitted.)

22 MR. O'CONNOR: May I display this page to the jury,
23 Your Honor?

24 THE COURT: Yes.

11:16:38 25 MR. O'CONNOR: Thank you.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:16:39 1 BY MR. O'CONNOR:

2 Q Dr. McMeeking, this is a document of testing, Bard's
3 testing, that you looked at and one that you saw. Who else
4 would -- well, let me ask you this: These are Bard tests that
11:16:56 5 Bard used for their filters before they released them;
6 correct?

7 A That's correct.

8 Q And what is it about what we're looking at, if you could
9 walk us through page 13 that supports your opinion that this
11:17:10 10 test was inadequate and didn't give any better information
11 about problems that the filters were experiencing?

12 A Well, this -- these results showed the results that were
13 obtained for the G2 Express and what we -- what it was telling
14 me, in conjunction with another document, is that the test was
11:17:32 15 a bad test.

16 Q How so?

17 A Because there's -- there's another document, which is the
18 report of the test that was carried out for the Eclipse. So
19 about just over a year later the test was repeated for the
11:17:49 20 Eclipse filter and at the same time the G2 Express filter was
21 tested for comparison with the Eclipse.

22 Q All right. So I'm going to show you another exhibit, and
23 I don't know how to put them side by side, but is there
24 anything on this document that we should note when we go to
11:18:07 25 the next exhibit?

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:18:08 1 A So we should note that the column that's entitled "Mean,"
2 if you see that in the table, the number of cycles to failure
3 for the G2 Express is 668.3.

4 Q Can you circle what we should note.

11:18:28 5 A Oh. Yes.

6 So the one to look at -- I've circled two numbers.
7 The one to look at is the one for the G2 Express. And this is
8 the average number of doing this to the filter before three of
9 the arms failed.

11:18:48 10 Q All right. Is there anything else we should note about
11 your opinions at it relates to these findings here?

12 A I think that's it for this document.

13 Q All right. So we'll hold that thought and then let's go
14 to Exhibit 8359.

11:19:09 15 We're seeing a cover document. This is -- can you
16 tell us what the title of this document is.

17 A Title of this document is DV&V Vail Arm Fatigue Evaluation
18 Test Report.

19 Q All right. And did you learn the Vail is actually the
11:19:28 20 Eclipse?

21 A Yes. The Vail was a name that was used earlier on for the
22 Eclipse. It was eventually renamed the Eclipse. It was --

23 Q I'm sorry. Go ahead.

24 A I was going to say Vail was used during the development
11:19:41 25 steps. But the filter was released as the Eclipse.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:19:47 1 MR. O'CONNOR: And, Felice, can we go to page 9,
2 please.

3 BY MR. O'CONNOR:

4 Q Do you recognize page 9?

11:20:01 5 A I do.

6 Q And is this a test, an actual document you reviewed, in
7 rendering your opinions in this case?

8 A I did.

9 Q And did you report your opinions about this document?

11:20:11 10 A I did.

11 MR. O'CONNOR: I move to admit Exhibit 8359.

12 MS. HELM: No objection, Your Honor.

13 THE COURT: Admitted.

14 (Exhibit 8359 admitted.)

11:20:19 15 BY MR. O'CONNOR:

16 Q All right. Dr. McMeeking, we noted what you asked us to
17 note earlier. Now put it all together and tell us what is the
18 significance of this document, please.

19 A So the table in this document shows the results from the
11:20:32 20 later test in which the Eclipse, known as the Vail, was given
21 the saluting arm test, and the G2 Express, now called the G2X,
22 was given the same test at this time. So it was tested a
23 second time just over a year later.

24 And the information I want to draw your attention to
11:20:56 25 is the mean number of cycles to failure of the G2X.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

1 THE COURT: Mr. O'Connor, it's not in front of the
2 jury.

3 MR. O'CONNOR: Oh. I apologize. I moved for
4 admission. May I display to this jury? Thank you.

5 THE COURT: You may.

6 MR. O'CONNOR: I apologize. I see it all the time
7 and I forget that it's not on everybody's TV.

8 BY MR. O'CONNOR:

9 Q Let's go back, Dr. McMeeking. What are we looking at
10 again?

11 A Can we erase the red circle?

12 We're looking at the results page of the document
13 that gives the results of the saluting arm test in which the
14 Eclipse and the G2 Express, now called the G2X, were tested
15 for the saluting arm failure process.

16 Q And what findings are significant?

17 A In the table, the results for both the Eclipse and G2X are
18 given. And I want to draw your attention to the results for
19 the G2X for the mean number of cycles before three arms of the
20 filter failed. And I've put a circle around it and you see
21 that that number is 440.

22 Q As compared to the earlier number?

23 A The number that came out of the test over a year earlier
24 was 668.3.

25 Q So was Bard using these results to somehow suggest that

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:22:31 1 the Eclipse was better?

2 A Yeah. They were -- they reported these results to
3 indicate that the Eclipse was significantly better than the
4 G2X.

11:22:44 5 Q In your opinion, is that reliable for anybody expecting a
6 company like Bard to adequately test its devices before
7 putting them out there in the market?

8 A Yes, one would expect them to test the filters in a
9 reliable way. And a point about this comparison is that

11:23:02 10 this -- the number of 440 cycles to failure is so different
11 from 668.3 that it calls into question whether the test even
12 tests anything in a meaningful way.

13 If the test was reliable, the number that came out of
14 the test for the G2X would have been more similar to the
11:23:23 15 number that came out on the previous test for the G2 Express.
16 In other words, more like 668.

17 Q And should a goal of testing to be consistency?

18 MS. HELM: Your Honor --

19 THE WITNESS: It should be consistency and it should
11:23:37 20 mean something.

21 THE COURT: Excuse me. When she stands up to object,
22 please wait, Dr. McMeeking.

23 MS. HELM: Objection. Leading.

24 THE COURT: Sustained.

25

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:23:44 1 BY MR. O'CONNOR:

2 Q What should the goal of testing be?

3 A The goal of testing should be to obtain meaningful and
4 consistent and reliable results that give you useful

11:23:57 5 information about the problems and failure modes that can be
6 anticipated for devices such as filters.

7 Q Should this testing have any relationship to what may
8 happen in the real world?

9 A Yes. It's important for the testing to replicate as
11:24:14 10 closely as possible the conditions that the device, in this
11 case the filter, will experience when it's in its environment
12 and in the conditions that are imposed upon it when it's being
13 used.

14 Q Now, was it any more reasonable to use the saluting arm
11:24:34 15 test in 2009 or 2010 than it was in 2005?

16 A No, it was not any more reasonable then.

17 Q Was there any reason why Bard in later years 2000 -- 2009
18 and 2010 would could rely on this test to assess fatigue and
19 fracture resistance?

11:24:56 20 A In my opinion -- in my opinion, it was just as unreliable
21 in 2010 as it was in the early days when it began -- when they
22 began to use it, and it does not represent anything
23 significant or broad about the fatigue resistance of the
24 various filters involved.

11:25:18 25 Q Now, let me ask you about Exhibit 5929.

DIRECT EXAMINATION (CONT'D) - ROBERT McMECKING

11:25:20 1 MR. O'CONNOR: Could we put that up.

2 BY MR. O'CONNOR:

3 Q Are you familiar with this document?

4 A I am.

11:25:46 5 Q And -- what page -- excuse me.

6 What are we looking at, Dr. McMeeking?

7 A We're looking at a test report document which is entitled
8 DV&V Flat Plate Fatigue and Corrosion Examination Test Report,
9 G2 Express Filter.

11:26:07 10 Q And have you reviewed this test and reported about this
11 test in stating your opinions?

12 A Yes, I have.

13 Q All right. I want you to look at --

14 MR. O'CONNOR: Well, I have it as 17 of 18, Felice,
11:26:24 15 but I don't have the corresponding Bates number.

16 BY MR. O'CONNOR:

17 Q Dr. McMeeking, have you reviewed 5929 at page 17?

18 A I have.

19 MR. O'CONNOR: I'd move for admission of this
11:26:52 20 exhibit, Your Honor.

21 MS. HELM: No objection, Your Honor.

22 MR. O'CONNOR: May I display --

23 THE COURT: Excuse me.

24 Admitted.

09:25:03 25 (Exhibit 5929 admitted.)

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:27:00 1 MR. O'CONNOR: Thank you.

2 May I display to the jury this page?

3 THE COURT: You may.

4 BY MR. O'CONNOR:

11:27:06 5 Q Dr. McMeeking, this test was discussed at the beginning of
6 this case. Is there anything about this flat plate fatigue
7 and corrosion examination that establishes or proves that a
8 filter can survive in a human body for 77 years?

9 A No, it does not.

11:27:32 10 Q Explain to us.

11 A Well, this test was not carried out under worst-case
12 conditions. There was no -- again, it's a test where the
13 filter is put in a tube and then squeezed between flat plates.
14 The filter was not tilted. The filter was not perforated
11:27:51 15 through the wall of the simulated vena cava. And the filter
16 was not endothelialized to the wall of the -- of the tube.
17 And so this test did not -- it was not carried out under
18 worst-case conditions and therefore it cannot be used to
19 properly claim any survival life of any sort for the filter.

11:28:14 20 Q Now, I don't want to talk about rates and I don't want to
21 talk anything about that, but I do want to talk about this:
22 You did your calculations, you did your analysis, and you
23 learned and found out about how these filters would fail under
24 worst-case conditions; correct?

11:28:33 25 A That's correct.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:28:34 1 Q And in your research, did you find support out there that
2 showed that the filters were failing?

3 A I did.

4 Q Bard filters were failing consistent with your -- were
11:28:44 5 they failing consistent with your calculations?

6 A That's correct. I found that they were failing by
7 tilting, failing by perforating the wall of the vena cava, and
8 they were failing by experiencing fatigue fractures after they
9 had been implanted in patients.

11:29:01 10 Q Now, in your report, did you set forth opinions on
11 features that could prevent or reduce those type of failure
12 modes?

13 A I did.

14 Q And what are those?

11:29:12 15 A Those features are that two-tier --

16 MR. O'CONNOR: We can take this down.

17 THE WITNESS: -- a two-tier design such as used in
18 the Simon Nitinol filter --

19 MS. HELM: Excuse me --

11:29:26 20 THE WITNESS: Can we have the Elmo on?

21 MS. HELM: Excuse me. Your Honor, may we approach?

22 THE COURT: Yes.

23 Feel free to stand up if you want to, ladies and
24 gentlemen.

11:29:33 25 (Bench conference as follows:)

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:29:46 1 MS. HELM: Nowhere in his reports has he offered an
2 alternative design as a two-tier design. He's said that the
3 Simon Nitinol is an alternative design, but he's now
4 testifying to a filter like the Simon Nitinol.

11:29:59 5 When I raised this with Mr. O'Connor before we
6 started today, he said he wasn't going to offer that opinion.
7 So --

8 MR. O'CONNOR: He's going to talk about his opinions
9 on caudal anchors, he's going to talk about his opinions on
11:30:12 10 the chamfer, and he's going to talk about his opinions on
11 perforation limiters. All listed and set forth in his report.

12 THE COURT: Well, he just talked about a two-tier
13 design. Is that in his report?

14 MR. O'CONNOR: Yes.

11:30:25 15 THE COURT: Can you show it to me?

16 MR. O'CONNOR: Do we have --

17 It's a repeat of what he said on Simon Nitinol.

18 THE COURT: He didn't talk about Simon Nitinol. He
19 said a two-tiered design would be an improvement.

11:30:37 20 MR. O'CONNOR: That's what he's referring to.

21 THE COURT: Then I think he should clarify he's
22 talking about the Simon Nitinol.

23 MR. O'CONNOR: Then I'm going to have talk about
24 caudal anchors, the chamfer, and the perforation limiters.

11:30:48 25 THE COURT: All right. If he clarifies the two-tier

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

1 means the Simon Nitinol, that addresses your issue.

2 MS. HELM: As long as it's the Simon Nitinol.

3 MR. O'CONNOR: That's fine.

4 THE COURT: Okay. So clarify that and you can move
5 on.

6 (Bench conference concludes.)

7 THE COURT: Thank you.

8 BY MR. O'CONNOR:

9 Q Dr. McMeeking, I just wanted to talk about -- clarify
10 something for everybody here and the members of the jury.

11 The two-tier design is what you talked about when you
12 talked about the Simon Nitinol filter is a safer filter.

13 A That's correct.

14 Q All right. Now, what about caudal anchors? Did you
15 report on those?

16 A I did.

17 Q What are caudal anchors?

18 A Caudal anchors are features on the filter.

19 May I have the Elmo on again, please.

20 Again, if you look at the Eclipse filter, you can see
21 at the left end where we have the feet on the legs there are
22 hooks. These hooks are designed to hook into the wall of the
23 vena cava and that will help to stop the filter moving in this
24 direction. Because to move in this direction, you have to
25 work against the shape of the hooks.

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

1 Caudal anchors are hooks that point in the opposite
2 direction, so that if the filter wants to move that way, the
3 hooks will inhibit that motion.

4 Q All right. And that would, in your opinion, reduce or
5 prevent which failure mode?

6 A It would reduce and help to eliminate the failure mode of
7 caudal migration, and it would reduce and help to eliminate
8 the fault of tilting. Because when the filter tilts, it needs
9 to move some of its limbs in the caudal direction, even if
10 some of the limbs go in the upwards direction. It's called
11 cephalic. Cephalic, caudal.

12 So the caudal anchors will help to inhibit tilt as
13 well as caudal migration. And since tilt contributes to
14 perforation, that will help to reduce the degree of
15 perforation. And since perforation contributes to fatigue
16 fracture, that will help to reduce the incidence of fatigue
17 fracture.

18 Q Now, you also talked about the chamfer.

19 A Correct. Correct.

20 Q And what, in your opinion, should be done to the chamfer
21 to make it safer?

22 A The chamfer should be made gentler.

23 Q That's the edge of the cap?

24 A Edge of the cap. I'll show this illustration again.

25 The situation in the filters that we're discussing is

DIRECT EXAMINATION (CONT'D) - ROBERT McMECKING

11:33:58 1 like that. But as making it like that would be a much better
2 situation, a much safer situation, and would help to reduce
3 the incidences of fatigue failures that would be experienced
4 by the filter.

11:34:14 5 And a point to make is that the Simon Nitinol filter
6 has such a feature in its cap. Where the top wires come out
7 of the top cap there is a breaking of the edge that has the
8 same effect as I'm talking about with this gentler rounding of
9 the surface.

11:34:41 10 Q And then in terms of penetration limiters, what is your
11 opinion on those?

12 A My opinion on penetration limiters is that they would help
13 because they would help to reduce how much perforation and
14 penetration was taking place in the filter. And that would
11:35:00 15 contribute to reduction in the problems the filters have with
16 fatigue fracture because fatigue fracture is a consequence
17 often of perforation. And because perforation contributes to
18 tilt, it would have contributed to reducing how much tilt the
19 filters were experiencing as well.

11:35:26 20 Q Dr. McMeeking, you told us earlier that the G2, the G2X,
21 like the Recovery, and the Eclipse were marketed as permanent
22 filters; correct?

23 A That's correct.

24 Q Do you have an opinion whether the design flaws that you
11:35:48 25 have determined exist in each of those filters, defective

DIRECT EXAMINATION (CONT'D) - ROBERT McMEEKING

11:35:53 1 designs, were consistent with a filter that should be stable
2 and remain in a patient's vena cava for the duration of her
3 life?

4 A It is my opinion these features of the filter are
11:36:05 5 inconsistent with that objective.

6 Q And based upon the design, should Bard have known these
7 filters could fail at any time after implant?

8 A Yes.

9 Q Now, we talked about your opinions and your findings and
11:36:28 10 your calculations; correct?

11 A Correct.

12 Q And those opinions support what, in your mind, are
13 defective designs in this filter?

14 A That's correct.

11:36:38 15 Q And in your opinion, the defective design of the filter,
16 the G2, G2X, the Eclipse, the filter that Lisa Hyde
17 experienced, did those failures result from the defective
18 design?

19 A They do.

11:36:52 20 Q And do you attribute her failures that she experienced in
21 her filter, the penetration and the fracture, to the
22 inadequate testing that was done by Bard?

23 A I do.

24 Q And is the failures that Lisa Hyde's filter experienced,
11:37:05 25 contribute those to the improper internal assessments that

CROSS-EXAMINATION - ROBERT McMEEKING

11:37:10 1 you've talked about that were conducted by Bard?

2 A That's correct.

3 Q And you have reported your findings to Bard; is that
4 correct?

11:37:19 5 A Yes.

6 MS. HELM: Object to the form, Your Honor. Leading.

7 THE COURT: Sustained.

8 BY MR. O'CONNOR:

9 Q Have you given reports of all of your opinions to Bard?

11:37:26 10 A I have.

11 Q Is Bard welcome to take your opinions?

12 A Yes. They can use my results and use my reports and use
13 them as they see fit.

14 Q Have they?

11:37:34 15 A As far as I know, they have not.

16 Q And today are the opinions that you have talked to us
17 about, based upon all of the work you've done in this case,
18 opinions that you've reached to a reasonable degree of
19 engineering and scientific certainty?

11:37:51 20 A I have.

21 MR. O'CONNOR: That's all I have. Thank you.

22 THE COURT: All right. Thank.

23 Cross-examination.

24 MS. HELM: Thank you, Your Honor.

25

CROSS-EXAMINATION - ROBERT McMECKING

11:38:00 1 C R O S S - E X A M I N A T I O N

2 BY MS. HELM:

3 Q Good morning, Dr. McMeeking.

4 A Good morning.

11:38:22 5 Q My name is Kate Helm. I don't think we've ever met.

6 A I don't believe we have, no.

7 Q Nice to meet you.

8 A Nice to meet you.

9 Q I'm going to start off and talk a little bit about your

11:38:31 10 experience with IVC filters before we get into your opinions.

11 You have no experience with IVC filters outside of

12 your work as a consultant in this case; is that correct?

13 A That's correct.

14 Q And you are -- you're published. You've published

11:38:49 15 articles. But you have never published an article about an

16 IVC filter, have you?

17 A I have not.

18 Q You've never submitted a publication for peer review about

19 an IVC filter?

11:38:59 20 A No, I have not.

21 Q And independent of your work as a retained expert witness

22 in this case and in litigation against Cook, another

23 manufacturer, you have never performed an analysis of an IVC

24 filter, have you?

11:39:14 25 A Outside of the litigation sphere, I have not.

CROSS-EXAMINATION - ROBERT McMEEKING

11:39:18 1 Q Okay.

2 And other than your work as a paid expert in this
3 case and your work as a paid expert for the plaintiffs in the
4 Cook litigation, you have never been involved in any testing
11:39:31 5 of an IVC filter; correct?

6 A That's correct.

7 Q And, of course, you have never conducted or been involved
8 in any clinical studies of an IVC filter, have you?

9 A That's correct.

11:39:41 10 Q You are not a biomedical engineer, are you?

11 A No, I'm not.

12 Q You're not a medical doctor?

13 A I'm not.

14 Q And you are not an expert on when and which IVC filters
11:39:56 15 should be used in a patient, are you?

16 A I'm not such an expert.

17 Q And you've obviously never placed or retrieved an IVC
18 filter, have you?

19 A I have not.

11:40:09 20 Q And just so we're clear, you do calculations in theory;
21 correct?

22 A That's correct.

23 Q You do not test; correct?

24 A I do not do bench tests.

11:40:18 25 Q Okay. You don't do bench tests, you don't do animal

CROSS-EXAMINATION - ROBERT McMEEKING

11:40:22 1 tests, you don't do any testing beyond calculations; correct?

2 A That's correct.

3 Q You don't design products?

4 A I do not.

11:40:32 5 Q You don't test products?

6 A I do not do bench tests of products.

7 Q You don't do any testing beyond calculations and FEA

8 analysis; correct?

9 A No, I do not. But when I'm consulting for medical implant

11:40:47 10 companies, I review and support and advise on the bench

11 testing that those companies do.

12 Q You've never set up a bench test?

13 A I have not done that personally, no.

14 Q You have never set the protocol for a bench test?

11:41:05 15 A No, I have not.

16 Q You've never set up an animal study?

17 A No, I have not.

18 Q You've never set up the protocol for an animal study?

19 A I have not.

11:41:13 20 Q You have never taken those studies, those protocols, and

21 actually applied them to the product at issue, have you?

22 A No, I have not.

23 Q And what you did in this case was you went back and looked

24 at what Bard did; correct?

11:41:29 25 A Yes, that's correct.

CROSS-EXAMINATION - ROBERT McMEEKING

11:41:30 1 Q And you had available to you all of the testing that Bard
2 did; correct?

3 A I believe I did, yes.

4 Q You had Bard's FEA analysis available to you?

11:41:41 5 A Correct.

6 Q You had bard's bench test available to you?

7 A Correct.

8 Q You had Bard's animal tests available to you?

9 A I had it available to me, yes, that's correct.

11:41:49 10 Q Okay. You had Bard's radial strength test available to
11 you; correct?

12 A I have the results and reports on that, yes.

13 Q You haven't spoken to this jury at all today about Bard's
14 animal testing, have you?

11:42:01 15 A No, I have not.

16 Q You have not spoken to this jury today at all about Bard's
17 radial strength testing, have you?

18 A I have not, no.

19 Q You've spoken about a few isolated tests out of hundreds
11:42:12 20 that were run on these IVC filters; correct?

21 A Correct. I have spoken about ones which are very
22 important.

23 Q But you've never -- you haven't told this jury anything
24 about those hundreds of other tests, have you?

11:42:24 25 A That's correct.

CROSS-EXAMINATION - ROBERT McMEEKING

11:42:24 1 Q You haven't told them anything about the radial strength
2 test, have you?

3 A That's correct.

4 Q You haven't told them about anything about the animal
11:42:31 5 testing that was done on the Recovery, the G2, the G2X, or the
6 Express -- or the Eclipse filters; correct?

7 A That's correct.

8 Q Now, you've come in here today and you've told this jury
9 that Bard filters can fail from tilt, perforation, migration
11:42:50 10 and fracture; correct?

11 A That's correct.

12 Q Those four problems that you've told the jury about today
13 are same conditions that can occur in other manufacturers'
14 filters, aren't they?

11:43:02 15 A That's correct.

16 Q So Bard is not unique in the retrievable filter market for
17 those conditions; correct?

18 MR. O'CONNOR: Objection, your Honor. May we
19 approach the bench?

11:43:12 20 THE COURT: Yes.

21 If you want to stand up, feel free.

22 (Bench conference as follows:)

23 MR. O'CONNOR: Here's the problem. When they ask
24 those kind of questions, our expert is locked in to not being
11:43:31 25 able to talk about what he knows about breaks and what he

CROSS-EXAMINATION - ROBERT McMEEKING

1 knows about these filters and how Bard filters fare compared
2 to the other filters.

3 THE COURT: Therefore?

4 MR. O'CONNOR: Therefore I think she opened the door
11:43:43 5 and that we should be able to have our experts, including
6 Dr. McMeeking, to rehabilitate himself and say, well, I do
7 know that Bard filters are worse than other filters.

8 MS. HELM: My question was simply Bard was not unique
9 in having those four failure modes. That's what I said. I
11:44:02 10 said they have these four failure modes, other filters have
11 these four failure modes, Bard is not unique.

12 I'll go back and clarify it and say I'm talking about
13 the fact these failure modes exist in other filters and he has
14 seen it.

11:44:17 15 THE COURT: Well, but here's my response,
16 Mr. O'Connor. You said in your opening, and you're going to
17 have experts talk about comparative rates of failure. This
18 guy isn't an expert on that subject and all he can do is
19 repeat what others say.

11:44:28 20 So what I think we should do is you can, on
21 cross-examination or redirect examination, say Ms. Helm asked
22 you if these other kinds of failures occur in other filters.
23 She didn't ask you about rates and you understand there are
24 other experts who will address rates.

11:44:47 25 And that way the jury understands that it's not that

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11:44:50 1 you don't have an answer to it, it's just not this expert that
2 can give it.

3 MR. O'CONNOR: Okay. That's a fair solution.

4 MS. HELM: Thank you, Your Honor.

11:44:57 5 MR. O'CONNOR: Thank you, Your Honor.

6 (Bench conference concludes.)

7 BY MS. HELM:

8 Q Dr. McMeeking, you are well aware that perforation, tilt,
9 fracture, and migration are known to occur in all IVC
11:45:27 10 retrievable filters; correct?

11 A I'm not aware it happens in all, but I know it happens in
12 many.

13 Q Engineers, in designing a product, have to perform a
14 risk/benefit analysis; correct?

11:45:41 15 A That's correct.

16 Q It's part of what they do almost every day; correct?

17 A That's correct.

18 Q And they look to reduce risks; correct?

19 A That's correct.

11:45:52 20 Q And you can't -- you agree with me that in a retrievable
21 IVC filter you cannot reduce the risks to zero?

22 A I'm not sure if that's the case, but I would say that it's
23 difficult -- would be very difficult to reduce to zero. But
24 nevertheless, one should reduce the risks as much as feasible.

11:46:12 25 Q You are not aware of any implantable medical device that

CROSS-EXAMINATION - ROBERT McMEEKING

11:46:16 1 is 100 percent risk free, are you?

2 A I don't know if that's the case because I'm not familiar
3 with all medical implant devices.

4 Q The ones you're familiar with do not have zero risk; is
11:46:26 5 that correct?

6 A That's correct.

7 Q And that's why a manufacturer has to design and build a
8 product balancing the risks and benefits of the product;
9 correct?

11:46:34 10 A Correct.

11 Q You came in today and you offered to this jury four
12 alternative designs to the Bard G2, G2X, and Express filters;
13 correct?

14 A Correct.

11:46:55 15 Q First alternative design -- I'm actually going to skip the
16 first one.

17 The second alternative design, the one you came in
18 with, was a caudal anchor; correct?

19 A Correct.

11:47:07 20 Q You have no design of a caudal anchor, do you?

21 A I have not designed one myself, no.

22 Q You have not performed any calculations on a caudal anchor
23 that you propose, have you?

24 A No, I have not.

11:47:18 25 Q You have not performed any FEA analysis on a caudal anchor

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11:47:21 1 that you proposed, have you?

2 A No, I have not.

3 Q You have not performed any testing on a filter with a
4 caudal anchor, have you?

11:47:29 5 A No, I have not.

6 Q So what you came in today with is an idea that a caudal
7 anchor might have a positive effect; correct?

8 A It is an assessment from an engineering perspective that
9 it would have beneficial effects.

11:47:45 10 Q It's an engineering assessment not based on any
11 calculations, any finite element analysis, any design drawings
12 or any testing; correct?

13 A That's correct.

14 Q I'm going to ask you that same question about penetration
11:47:58 15 limiters. You didn't come in here today and bring a design of
16 a filter with penetration limiters, did you?

17 A That's correct.

18 Q You didn't do any calculations or finite element analysis
19 about a filter with penetration limiters, did you?

11:48:12 20 A No, I did not.

21 Q And you didn't do a design drawing of a filter with
22 penetration limiters and show it to the jury, did you?

23 A No, I did not.

24 Q So what you came in today with was an idea about
11:48:24 25 penetration limiters as an alternative design for an IVC

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11:48:27 1 filter; correct?

2 A That's correct.

3 Q Okay.

4 The same thing with your gentler curve out of the
11:48:38 5 cap. You know --

6 A Yes.

7 Q -- that you explained to the jury. And you drew a
8 picture, but you haven't done any calculations or analysis of
9 what that curve should be, have you?

11:48:48 10 A Yes, I have.

11 Q You have?

12 A Yes.

13 Q Did you bring those calculations with you today?

14 A I did not bring them except they're in my report, so
11:48:56 15 they're sitting here today.

16 Q But you haven't tested that analysis to determine whether
17 your calculations are valid, have you?

18 A I have not carried out any bench tests of that concept.

19 Q So, again, you come in today with ideas that caudal
11:49:14 20 anchors, penetration limiters, and a change in the angle could
21 make a difference in the IVC filters; correct?

22 A That's correct, but I will add that breaking sharp corners
23 is a standard aspect of design against fatigue.

24 Q Okay. You have not studied at all what could be done to
11:49:38 25 reduce or prevent fracture, tilt, perforation, or migration in

CROSS-EXAMINATION - ROBERT McMEEKING

11:49:44 1 the Bard IVC filters, have you? You have performed no
2 testing, no analysis, no calculations using your ideas, have
3 you?

4 A I'm not sure I understand your question. Can you restate
11:49:56 5 it again.

6 Q I'll try again. Your proposal is to add caudal anchors,
7 penetration limiters, and change the angle of a Bard
8 retrievable IVC filter; correct?

9 A Correct.

11:50:06 10 Q You have done no studies, no testing or analysis as to
11 whether your ideas would have the benefit that you think they
12 would have; correct?

13 A That's correct.

14 Q And you've done no testing or analysis -- let me back up.

11:50:22 15 What is an unintended consequence in a -- from an
16 engineering perspective?

17 A From an engineering perspective it's a problem caused by a
18 step taken in a design that was not anticipated.

19 Q So you haven't done any analysis, no calculations, no
11:50:41 20 finite element analysis, no testing at all to determine
21 whether your ideas of caudal anchors, penetration limiters,
22 and the change in the angle coming out of the cap would have
23 unintended consequences on the Bard IVC filters, have you?

24 A No, I have not done such an investigation.

11:51:02 25 Q Okay. I want to make sure. You've done no design, you've

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1 done no calculations, you've done no finite element analysis,
2 you've done no testing, you haven't created a prototype. You
3 don't know whether your ideas will actually work or not from
4 an engineering perspective, do you?

5 MR. O'CONNOR: Objection. Asked and answered.

6 THE COURT: Sustained.

7 BY MS. HELM:

8 Q Are you aware of any retrievable IVC filter that existed
9 in February or March of 2011 that had caudal anchors and
10 penetration limiters?

11 A I'm not aware of any such filter. Although I'm aware of
12 permanent filters that have some of those features.

13 Q But you're not aware in 2011 of any such filter, are you?

14 A Sorry? Say that again.

15 Q You're not aware of any such filter that had those
16 features in 2011, are you?

17 A Well, the Bird's Nest filter had features that act as
18 caudal anchors, and that filter has been around since the
19 1990s.

20 Q And that's a permanent filter; right?

21 A Yes.

22 Q Let's talk about the difference between -- and
23 Mr. O'Connor kept saying these are permanent filters. But
24 let's talk about the difference between a permanent filter and
25 a retrievable filter. Because there is a difference, isn't

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11:52:25 1 there?

2 A Yes.

3 Q And the Simon Nitinol, for example, is a permanent filter;
4 correct?

11:52:33 5 A That's correct.

6 Q It is not designed to be retrieved percutaneously;
7 correct?

8 A That's correct.

9 Q The G2, the G2X, and the Eclipse are retrievable filters;
11:52:46 10 correct?

11 A They're optional filters, which means they're for
12 permanent use and for retrievable use.

13 Q And the difference is the G2X and the Eclipse can be
14 retrieved percutaneously; correct?

11:53:01 15 A That's correct, but they must also be safe for use as
16 permanent filters.

17 Q Okay. You are not offering the opinion in this case that
18 the Simon Nitinol filter would have been a safer filter for
19 Mrs. Hyde, are you?

11:53:17 20 A I'm not offering any patient-specific opinions.

21 MR. O'CONNOR: That was covered and that's beyond the
22 course -- the scope of my examination. I adhered to what we
23 discussed earlier.

24 THE COURT: Well, let's talk about that on the break.

11:53:29 25 I think she can establish the limits of what that's -- what

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11:53:33 1 his opinion was.

2 BY MS. HELM:

3 Q Dr. McMeeking, you agree that if a doctor wants his
4 patient to have a retrievable or temporary filter,

11:53:46 5 Simon Nitinol is not an option. You agree with that, don't
6 you?

7 A Since it's a permanent filter, that would indicate it
8 shouldn't be used as a retrievable filter.

9 Q And you were aware that the physician who implanted
11:53:58 10 Ms. Hyde's filter wanted a temporary or retrievable filter,
11 aren't you?

12 A I'm not aware of the advice or anything that was given to
13 the patient, to Mrs. Hyde.

14 MS. HELM: Scott, can you pull up 8697, please.

11:54:17 15 And can you highlight where it says "Procedure."

16 Your Honor, this is in evidence. May I display,
17 please?

18 THE COURT: Yes.

19 BY MS. HELM:

11:54:25 20 Q Dr. McMeeking, I represent to you this is a radiology
21 report for the implant of Ms. Hyde's IVC filter. Do you see
22 there where it says "Procedure. Inferior vena cavagram and
23 temporary IVC filter"?

24 A I do.

11:54:44 25 Q So if Ms. Hyde's doctor wanted to implant a temporary or

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11:54:49 1 retrievable filter, the Simon Nitinol would not be an option;
2 correct?

3 MR. O'CONNOR: Objection. Lack of foundation as to
4 what Ms. Hyde's doctors felt or thought or wanted to do.

11:54:59 5 THE COURT: Overruled. He's not asking the
6 witness -- she's not asking the witness to testify on that.

7 THE WITNESS: Can you ask the question again, please.
8 BY MS. HELM:

9 Q Sure. So if doctor -- if Ms. Hyde's doctor who implanted
11:55:11 10 the filter wanted a temporary or retrievable IVC filter, the
11 Simon Nitinol is not an option; correct?

12 A According to the manner in which it should be used, no,
13 it's not an option.

14 Q Okay. At the beginning of the case the jury saw an
11:55:25 15 animation of the retrieval of a retrievable filter. And they
16 showed how it was designed to collapse as it was removed. The
17 Simon Nitinol has that cage on top that you've shown the jury;
18 correct?

19 A That's correct.

11:55:42 20 Q That cage is not designed to collapse when it was --
21 allowing it to be retrieved; correct?

22 A That's correct.

23 Q What you said was the advantage of the Simon Nitinol
24 filter was that cage and it was stiffer; correct?

11:55:57 25 A That's one of its advantages.

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11:56:00 1 Q And that, that advantage, is one of the things that
2 prevents the Simon Nitinol from being a retrievable filter;
3 correct?

4 A That's correct.

11:56:08 5 Q Okay. And you would agree with me that the Simon Nitinol
6 is a fundamentally different filter than the G2X or the
7 Express; wouldn't you?

8 A I'm not sure I would say fundamentally. It is rather
9 different, I would say.

11:56:22 10 Q If you've given testimony it is a fundamentally different
11 filter, you don't contest that, do you?

12 A I guess -- I don't contest it.

13 Q Okay.

14 The beginning of the test -- of your testimony, you
11:56:34 15 talked about proper engineering analysis. Do you recall that?

16 A I do.

17 Q Okay. And you testified that you approached your work as
18 a paid expert in the same way, using proper engineering
19 analysis; correct?

11:56:48 20 A That's correct.

21 Q And some of your opinions on the Bard retrievable filters,
22 you performed calculations and finite elements analysis;
23 correct?

24 A That's correct.

11:57:02 25 Q But you reached your conclusion that the Simon Nitinol is

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11:57:07 1 a safer filter based on just looking at the filter and
2 diagrams of the filter; correct?

3 A That's not completely true. I did calculations to
4 estimate the stiffness of the features on it.

11:57:21 5 Q You did calculations to estimate the stiffness, but you
6 did not perform any FEA or computer modeling of the
7 Simon Nitinol, did you?

8 A That's correct.

9 Q And you didn't perform any calculations to compare the
11:57:37 10 issues that you say existed in the Bard retrievable filters
11 with the Simon Nitinol filter, did you?

12 A Could you repeat the question?

13 Q You know what, I'll move on.

14 I'm going to switch gears a little bit. I mentioned
11:58:03 15 a few minutes ago that Bard isn't the only IVC filter
16 manufacturer you've criticized; is that correct?

17 A That's correct.

18 Q You also are testifying and have been retained by the
19 plaintiffs to testify against Cook Medical, an IVC filter
11:58:18 20 manufacturer; correct?

21 MR. O'CONNOR: Your Honor, I object to the form of
22 the question. I can explain at a break.

23 THE COURT: Hold on just a minute.

24 Yeah, let's come back to that after the break.
25

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11:58:33 1 BY MR. O'CONNOR:

2 Q You've testified either live or by video in two lawsuits
3 against Cook; correct?

4 A That's correct.

11:58:43 5 Q And in those trials you testified you believed the Cook
6 filter was defective in design; correct?

7 A That's correct.

8 Q In that litigation you also criticized the testing
9 performed by Cook when they were designing their IVC filter;
11:58:55 10 correct?

11 A That's correct.

12 Q And as part of that criticism, you said Cook failed to
13 conduct adequate fatigue testing of their filter; is that
14 correct?

11:59:06 15 A That's correct.

16 Q And just like in this case, you also said in that
17 litigation that Cook failed to conduct worst-case scenario
18 testing; correct?

19 A That's correct.

11:59:19 20 Q In fact, you previously testified that Cook filters tilt
21 more than any other filters in the marketplace; correct?

22 A That's correct.

23 May I revise my answer? I said -- I believe I said
24 that they tilt more than other filters I'm aware of.

11:59:40 25 THE COURT: All right. We're going to break at this

11:59:41 1 point, ladies and gentlemen.

2 Because of a meeting I have to attend, we're going to
3 take a break until 1:15. We'll resume at that time. And I'll
4 excuse the jury.

11:59:50 5 (The jury exited the courtroom at 12:00.)

6 THE COURT: You can step down, Doctor.

7 THE WITNESS: Thank you.

8 THE COURT: Mr. O'Connor, you wanted to raise an
9 issue?

12:00:23 10 MR. O'CONNOR: I wanted to raise two issues.

11 THE COURT: You've got to be at the mic. At the mic.

12 MR. O'CONNOR: On the issue about the -- your ruling
13 at their request that Dr. McMeeking not testify about the
14 Simon Nitinol filter being appropriate for Mrs. Hyde, and this
12:00:42 15 attorney who made that motion went and used your order as a
16 sword and a shield against us.

17 THE COURT: Hold on on that, Mr. O'Connor.

18 First of all, your objection was that it was beyond
19 the scope of direct. That was the objection, which I don't
12:00:58 20 think is --

21 MR. O'CONNOR: May I clarify?

22 THE COURT: Let me point something out first.

23 In my *Daubert* motion they objected that Dr. McMeeking
24 is not qualified to opine that the Simon Nitinol filter would
12:01:09 25 have been a safer alternative for any particular plaintiff,

12:01:13 1 including plaintiffs in the bellwether cases, and your
2 response was that you agreed and you said that you would not
3 ask Dr. McMeeking to give that opinion.

4 So you agreed at that point that he would not give
12:01:26 5 any opinion about whether or not the Simon Nitinol was safer
6 for this plaintiff.

7 And I think in light of that, it's inappropriate --
8 it is appropriate for the defendants to point out that he's
9 not giving that opinion.

12:01:40 10 So with that in mind, let me hear your objection.

11 MR. O'CONNOR: And let me clarify one point. When I
12 made my objection earlier I had signaled to you I didn't want
13 to talk about this order in front of the jury and that I
14 thought I had at least conveyed enough to you that I thought
12:01:55 15 it would be more appropriate to talk about --

16 THE COURT: That's fine. That's why I'm listening to
17 you now.

18 MR. O'CONNOR: All right.

19 Your Honor, when they move in limine because they
12:02:03 20 believe evidence may ring a bell or may be so inadmissible and
21 a party agrees they won't bring that evidence, it's
22 inappropriate for them to use that agreement and somehow open
23 a door that they know we can't step through.

24 THE COURT: Mr. O'Connor, I'm not relying on an
12:02:19 25 agreement. I'm relying on the fact that at the *Daubert* motion

12:02:23 1 stage you agreed that this witness was not qualified to opine
2 that the Simon Nitinol was a safer filter for Ms. Hyde. You
3 agreed and said you wouldn't ask it.

4 Her question was, "You are not offering the opinion
12:02:39 5 in this case the Simon Nitinol filter would have been a safer
6 filter for Ms. Hyde." Exactly the point that you agreed he
7 couldn't state an opinion on. So what's the problem with
8 their pointing out that he's not stating that opinion?

9 MR. O'CONNOR: Because I think it is a manipulation
12:02:55 10 of our agreement. I think now they have opened the door
11 because I am pretty sure that we could talk to Dr. McMeeking
12 and he could say that, yeah, if I looked at that filter long
13 enough and had a discussion with her doctor, Mrs. Hyde's
14 doctor, maybe he would have understood what I was saying about
12:03:11 15 these filters.

16 I mean, it could open up a whole range of area and
17 testimony.

18 What we have tried to do, Your Honor, is act in good
19 faith and tried to narrow the issues in this case. But then
12:03:22 20 to allow this and make us pay for what was a reasonable
21 concession --

22 THE COURT: Hold on. Hold on. You agreed in your
23 *Daubert* motion response that he was not qualified to give that
24 opinion. So how can it now open the door to an opinion he's
12:03:37 25 not qualified to give?

12:03:39 1 MR. O'CONNOR: We also agreed that we would not raise
2 things like Dr. Moritz was retained by the defense. And it
3 would be inappropriate for us to ask that question if that
4 witness came here.

12:03:51 5 THE COURT: I think you're comparing apples and
6 oranges.

7 MR. O'CONNOR: Maybe I am. I just don't see it,
8 Your Honor. When we agree we're not going to open the door
9 and then they take that agreement to somehow try to impeach
12:04:04 10 him or whittle down his testimony, I think it's inappropriate,
11 Number 1. I stayed away from it on direct so it was beyond --

12 THE COURT: All right. We're going to move beyond
13 this point.

14 My ruling on this issue is --

12:04:15 15 Hold on, Mr. Stoller.

16 -- that you agreed at the *Daubert* motion stage, as
17 reflected on page 10 of my ruling, that Dr. McMeeking was not
18 qualified to opine on whether the Simon Nitinol filter would
19 have been better for Mrs. Hyde.

12:04:33 20 The defendants, I think, were able to point out he's
21 not giving an opinion on that issue. I think that's fair. I
22 don't think it opens any doors.

23 Now, what's the second issue that you wanted to
24 raise?

12:04:48 25 MS. REED ZAIC: Cook litigation.

12:04:49 1 MR. O'CONNOR: The Cook litigation. Not once but
2 twice she said "the plaintiffs retained you in Cook." "The
3 plaintiffs retained you in Cook."

4 I have a plaintiff sitting right here.
12:05:00 5 Go ahead.

6 MS. REED ZAIC: I believe at the outset at the
7 beginning of the line of questioning she said "these
8 plaintiffs" and then later she said "the plaintiffs" retained
9 you.

12:05:12 10 MR. O'CONNOR: Yes.

11 MS. REED ZAIC: The first one I couldn't hear if she
12 said "these plaintiffs" or "plaintiffs in Cook" --

13 THE COURT: I'll look at it. Hold on just a minute.

14 All right. So the question was: You've also
12:05:40 15 testified and have been retained by the plaintiffs to testify
16 against Cook Medical and IVC filter -- an IVC filter
17 manufacturer; correct?

18 Objection.

19 I said, "Let's come to that after the break." So
12:05:58 20 there was no answer.

21 The next question was, "You've testified live or by
22 video in two lawsuits against Cook."

23 The answer: "Correct."

24 Then she went on to talk about the opinions he's
12:06:11 25 given in Cook.

12:06:13 1 MS. REED ZAIC: There was an earlier reference to
2 "these plaintiffs." But that second one is the one that I
3 believe an objection was placed. And, Your Honor, if -- it's
4 absolutely inappropriate. She has not retained -- she doesn't
12:06:25 5 even have a lawsuit against Cook, and it is now insinuated to
6 the jury that she does.

7 THE COURT: Well, I've instructed the jury the
8 questions are not evidence. There was no answer to it because
9 I didn't let it be answered. So what are you suggesting we
12:06:39 10 do?

11 MS. REED ZAIC: I'm suggesting that we revisit that
12 and it be addressed because although there was no answer,
13 there is now an hour and 15 minutes with that question hanging
14 in the air.

12:06:50 15 THE COURT: All right.

16 Ms. Helm.

17 MS. HELM: The question wasn't answered. I can
18 rephrase the question and say "You were retained by the
19 plaintiffs in the Cook litigation."

12:07:05 20 THE COURT: Does that solve your problem, Ms. Reed
21 Zaic?

22 MS. REED ZAIC: I mean, there's not even foundation
23 to that question about whether that's even true that he's been
24 hired by anybody to testify against Cook.

12:07:15 25 THE COURT: Well, there doesn't need to be

12:07:17 1 foundation; He knows the answer.

2 MS. REED ZAIC: Right. But the message being sent to
3 the jury right now is that the plaintiff has a lawsuit against
4 another Cook -- another IVC filter company.

12:07:30 5 THE COURT: That was in the question, I agree. I
6 have told the jury that lawyers' questions are not evidence.
7 Do you want me to do more than that?

8 MS. REED ZAIC: I'd like to confer with counsel, but
9 I believe an instruction or something to obviate the fact that
12:07:42 10 the question has been withdrawn.

11 THE COURT: Okay. Well, obviously the question
12 hasn't been answered.

13 Go ahead and think about it. If there's something
14 you want me to do, I'll be happy to hear about that when we
12:07:53 15 come back.

16 But I think you should stay away from who retained
17 him in Cook.

18 MS. HELM: I will, Your Honor. Thank you,
19 Your Honor.

12:08:00 20 MR. O'CONNOR: And, Your Honor, I don't mean any
21 disrespect for this. Can I just make a little bit further
22 record on my first point just so the record's clear?

23 THE COURT: Yes, you can.

24 MR. O'CONNOR: The question also implies about
12:08:10 25 Mrs. Hyde and the Simon Nitinol filter to this jury, it

12:08:14 1 suggests that this maybe should have been something that
2 Dr. McMeeking should have considered and didn't. And so
3 that's the problem with the questions. They have a far range
4 of inferences that can be drawn.

12:08:55 5 THE COURT: So the question, again, was "You're not
6 offering the opinion that in this case the Simon Nitinol
7 filter would have been a safer filter for Ms. Hyde, are you?"

8 And his answer was, "I'm not offering any
9 patient-specific opinions."

12:09:18 10 I'm still not seeing the problem you're identifying,
11 Mr. O'Connor.

12 MR. O'CONNOR: Well, I mean, I made my record. I'm
13 glad you read that to me. At least he followed that directive
14 I gave him.

12:09:28 15 THE COURT: All right. We'll be back here at 1:15.

16 (Recess taken at 12:09.)

17 (End of a.m. session transcript.)

18 * * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 21st day of September, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter